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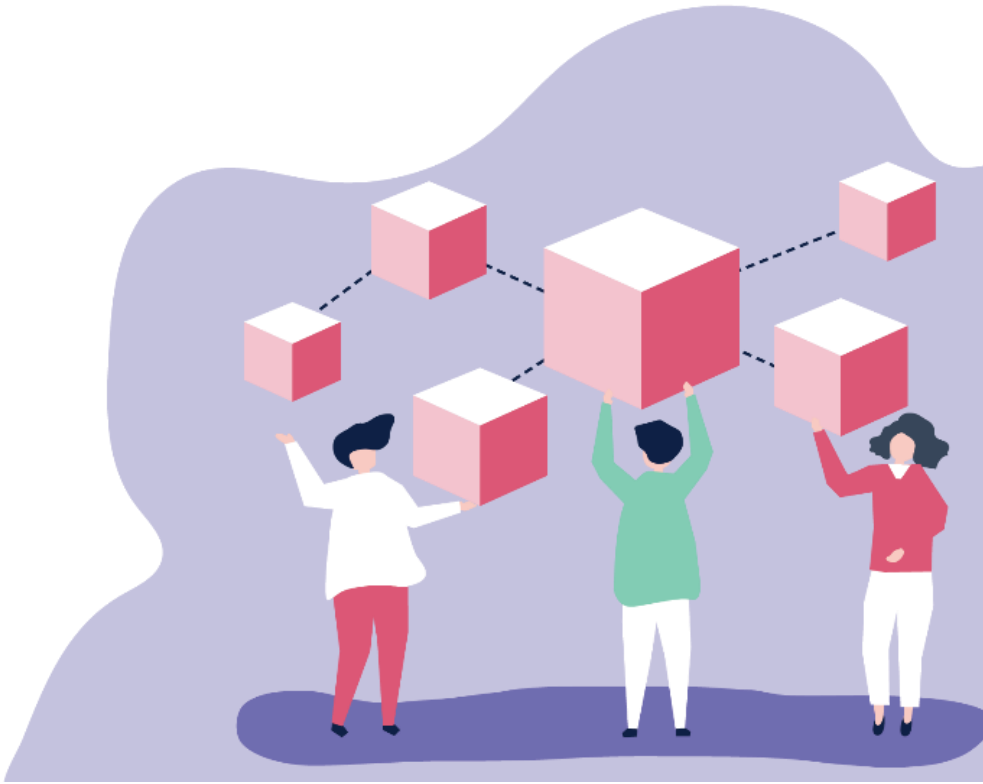
GATEKEEPER

D8.1.2 Overview of relevant standards in smart living environments and gap analysis

Deliverable No.	D8.1.2	**Due Date**	31/March/2021
Description	The document provides an updated overview of standards relevant for the Gatekeeper project and gap analysis.		
Type	R	**Dissemination Level**	PU
Work Package No.	WP8	**Work Package Title**	Standardisation and certification mechanisms
Version	1.0	**Status**	Final



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Abstract

The document provides an overview of international and some national standards being relevant for the GATEKEEPER project, as well as an overview of methodology regarding the collection of standards and an analysis of possible gaps in the available standards relevant to the project.

Statement of originality

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation or both.

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1. Introduction

The scope of this deliverable is an analysis of standards relevant to the GATEKEEPER project and identification of gaps between currently available standards and areas where standardisation would be relevant. It also deals with a possible revision of knowledge as gained in previous initiatives, including Research and Innovation projects and Internet of Things Large Scale Pilots, as well as envisioning of standardisation tracks for the GATEKEEPER project.

The document is a deliverable of WP8 Standardisation and certification mechanisms, more concretely of *Task 8.1 Analysis of relevant standards and gaps identification*, led by Funka. The relation between this WP and the rest of the GATEKEEPER project is illustrated as follows:

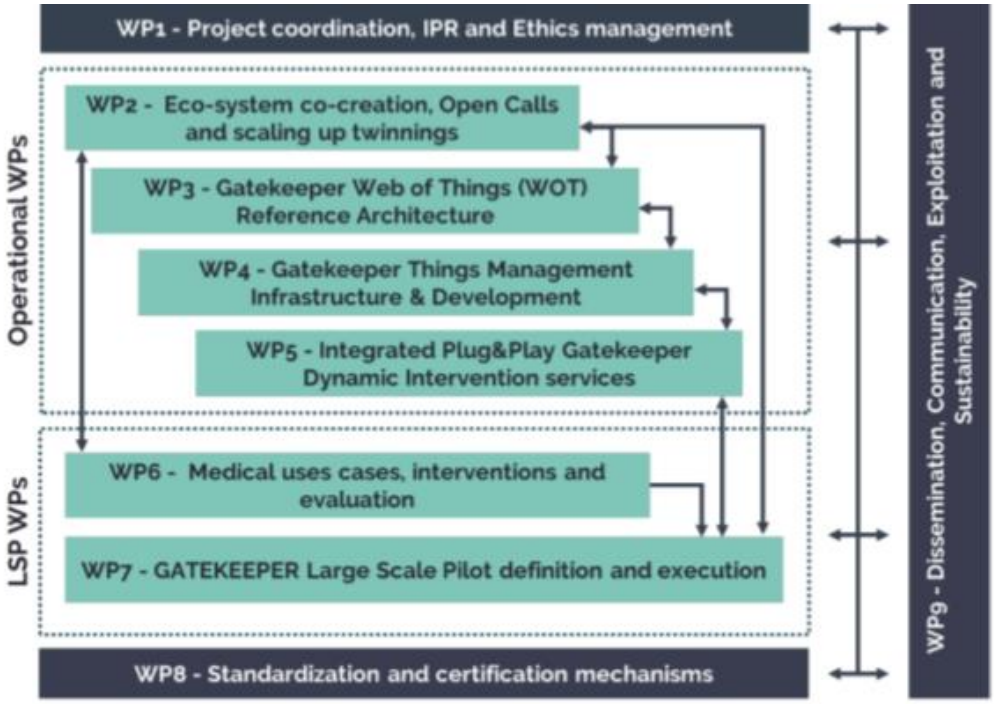

Figure 1 - WP structure

WP8 addresses standardisation and certification that is relevant for the other Work Packages in the GATEKEEPER project. This is specified in the description of the standards.

The standards listed in this document are selected according to their relevance for the GATEKEEPER project. The main categories of standards in are divided into the fields of:

- Home
- Health
- Assistive technology
- Information and communication technology and data
- AI services

The listing of standards is subdivided and is not following an orthogonal approach since one standard can be relevant for several of these categories. However, each standard will be listed once to avoid duplicate information.

The deliverable is dynamic as the list of standards will be continuously assessed and revised based on the lessons learned during the development of the project. Thus, the list will be continually evaluated, based on the developments and experiences of the GATEKEEPER project.

1.1 Updated version

As the first version of D8.1 was submitted before most of the technical developments in the project had started, it was agreed to update the deliverable at a later stage.

In this updated version, we have included the results of surveys as well as bilateral meetings and interviews not only with relevant technical partners, but also with the pilots, thereby including their experiences and needs when it comes to standards.

The following report is thus an update of the situation based on the status of the project.

2 Methodology

2.1 Introduction

The identification of relevant standards has been carried out through close collaboration with partners and pilots as well as desk research. In the updated version of the deliverable, the focus has been on making sure all aspects of the technical and business-related parts of the project have been covered when it comes to standardisation. This has been ensured by a combination of internal surveys and bilateral meetings, discussing the need or potential need for standards and certification of all partners and pilots.

In the updated version, all previously presented standards have been checked and validated to ensure they are presented in the most current and relevant versions.

2.1.1 Selection of standards

A study has been made on the data bases of CEN, CENELEC and ETSI at European level, and ISO and IEC at international level. Interoperability frameworks such as the European eHealth Interoperability Framework, and the Standards and Interoperability Framework have not been listed in this version of the overview. Products developed by other Standard Organisation Bodies e.g. IETF, IEEE, W3C, HL7, OMG and others considered relevant for the scope of the project have been also considered. Where known, relevant national standards have also been included. In addition, the EIP on AHA database for standards has been used, as well as other sources including reports.

2.1.2 Categories and classes of standards

The standards listed are mainly related to technical solutions and consider user friendliness and accessibility aspects and processes.

There are a variety of standards that cover different types of operability. In this overview, standards may belong to different classes but will be listed in only one of the classes.

Furthermore, there is a difference between process standards and standards for the technical specification of a device. We have therefore also included standards related to services where technical support is relevant. The standardisation categories will include:

- **Health**: standards for monitoring of health-related technology, measurement of bio-signals including web and mobile applications, person-facing e.g. video conference and messages, alerts etc, and wearable medical devices.
- **Home**: standards related to location systems, smart living environment, IoT-based solutions (e.g. daily activity monitoring), sensors at home (for fall detection etc.), home appliance services, environment control and Web of Things technology.
- **Personal autonomy – assistive technology**: standards relevant for certain types of assistive technology applicable for the GATEKEEPER project e.g. general requirements and test methods, robots and robotic devices, and sound transmission.
- **ICT and data**: standards related to web applications, smart phone applications, HTTPs, security mechanisms, as well as data collection, data storage, IoT, data collection, anonymisation mechanisms. Items include standards for user interface for laptop, mobile, tablets and voice assistants, as well as some standards on accessible home framework for the users regarding their well-being and safety. The accessibility standards are related to other types of standards, in particular ICT

and home related standards, to ensure that the design of the items that these standards cover, are made accessible to all.

2.1.3 Relation to the Work Packages

- WP2 Ecosystem value co-creation, Open Calls and scaling-up twinning is to create a viable user-led innovation ecosystem of partnering healthcare professionals, industry players and end-users, cutting across all four project spaces, aligned behind the objective of implementing and sealing GATEKEEPER solutions. The areas of standards relevant in WP2 will initially be:
    - Health
    - Medical equipment
    - Health related providers
    - Accessibility and user-friendliness for end-users
    - Trust and privacy
- WP3 GATEKEEPER Web of Things (WoT) Reference Architecture is to expand the WoT Reference Architecture. WoT related to healthcare and smart and healthy living at home. The WP3 is to support WP4 and WP5 on WoT, eHealth, mHealth, Big Data and AI. T3.3 will consider GATEKEEPER interoperable WoT standards over smart and healthy living at home domains, and maximising interoperability using existing and emerging standards and best practises across various services and smart home devices used by the pilots. Relevant standards in WP3 will be standards related to:
    - Healthcare
    - Home living
    - WoT
    - IoT and Smart Homes
    - Health care services
    - AI
- WP4: Things Management Infrastructure & Development. Based on WP3 the WP4 is to provide infrastructure and microservices required by WP5 to deliver an integrated GATEKEEPER ecosystem. Things refer here to platform, service system and application devices. Relevant standards will include standards on:
    - Data collection
    - Data storage
    - Smart home
    - Health related data – risk detection and interventions
- WP5: Integrated plug and play GATEKEEPER Dynamic Intervention services. This WP is based on WP4 and relevant standards will include:
    - Home Activity Monitoring and Health Activity Monitoring
    - AI-powered tools
    - Health, including:

        - Early detection and monitoring
        - Prevention and intervention
        - Robot services
        - Smart care
        - Care services
- WP6: Medical user cases, early detection and intervention. Standards relevant for this WP would include areas like:
    - Wearable and smart home IoT
    - Sensing equipment
    - Big Data and Data Analytics
    - Monitoring and prediction
    - Data analytics
- WP7: GATEKEEPER Large Scale Pilot definition and execution. Includes to define, manage and execute large sale pilot activities in different pilot sites, WoT architecture related to WP3 and user cases related to WP2. Relevant areas for standards will include:
    - User requirements
    - Technology development
    - Technological interoperability
    - Software artefacts
    - Medical requirements
        - Early detection
        - Early intervention
- WP9: Dissemination, Communication, Exploitation and Sustainability. Standards relevant for this WP, specifically the exploitation and new business model creation include areas such as:
    - Middle layer API
    - AI applications as products
    - New hardware products
    - Multi-sided platform components

3 Overview of relevant existing standards

3.1 Health

In the overview of standards on health we are referring to a broad concept, based on the World Health Organisation's definition of health - a state of complete physical, mental and social wellbeing, and not merely the absence of disease and infirmity. Thus, the listing includes e-Health, robotics and mHealth and ergonomics and several sub-groups of these.

3.1.1 Technical systems for monitoring the health condition, medical devices

Examples of relevant standards include blood sugar measurement, blood pressure measurement, etc. With increased opportunities for remote monitoring of health conditions and increased emphasis on the fact that older and other user groups should be able to stay home, more standards will be needed. Among other things, with increased use of welfare technology, standards that ensure communication between, for example, sensors and receivers when a person moves out of their own home and resides elsewhere, next to standardised equipment requirements. Universal design will be central to ensuring that all users can use the systems, such as audio-based information as an option for meters.

Number	Title	Relevant for WP
EN ISO 15197	In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus (ISO 15197:2013)	WP2, WP3, WP5, WP6, WP7, WP9
Description: This International Standard specifies requirements for in vitro glucose monitoring systems that measure glucose concentrations in capillary blood samples, for specific design verification procedures and for the validation of performance by the intended users. These systems are intended for self-measurement by lay persons for management of diabetes mellitus. This International Standard is applicable to manufacturers of such systems and those other organisations (e.g. regulatory authorities and conformity assessment bodies) having the responsibility for assessing the performance of these systems. This International Standard does not: provide a comprehensive evaluation of all possible factors that could affect the performance of these systems, pertain to glucose concentration measurement for the purpose of diagnosing diabetes mellitus, address the medical aspects of diabetes mellitus management, apply to measurement procedures with measured values on an ordinal scale (e.g. visual, semiquantitative measurement procedures), or to continuous glucose monitoring systems, apply to glucose meters intended for use in medical applications other than self-testing for the management of diabetes mellitus.		

EN ISO 14971	Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)	WP2, WP3, WP5, WP6, WP7, WP9
Description: This document specifies terminology, principles and a process for risk management of medical devices, including software as a medical device and in vitro diagnostic medical devices. The process described in this document intends to assist manufacturers of medical devices to identify the hazards associated with the medical device, to estimate and evaluate the associated risks, to control these risks, and to monitor the effectiveness of the controls. The requirements of this document are applicable to all phases of the life cycle of a medical device. The process described in this document applies to risks associated with a medical device, such as risks related to biocompatibility, data and systems security, electricity, moving parts, radiation, and usability. The process described in this document can also be applied to products that are not necessarily medical devices in some jurisdictions and can also be used by others involved in the medical device life cycle. This document does not apply to: — decisions on the use of a medical device in the context of any clinical procedure; or — business risk management. This document requires manufacturers to establish objective criteria for risk acceptability but does not specify acceptable risk levels. Risk management can be an integral part of a quality management system. However, this document does not require the manufacturer to have a quality management system in place. **NOTE: Guidance on the application of this document can be found in ISO/TR 24971[9].**		
IEC 60479-1	Effects of current on human beings and livestock - Part 1: General aspects	WP2, WP3, WP5, WP6, WP7
Description: IEC 60479-1:2018(E) provides basic guidance on the effects of shock current on human beings and livestock. This basic safety publication is primarily intended for use by technical committees in the preparation of standards in accordance with the principles laid down in IEC Guide 104 and ISO/IEC Guide 51. It is not intended for use by manufacturers or certification bodies.		
IEC 62366-1	Medical devices - Part 1: Application of usability engineering to medical devices	WP2, WP3, WP7, WP9
Description: IEC 62366-1:2015 specifies a process for a manufacturer to analyse, specify, develop and evaluate the usability of a medical device as it relates to safety. This usability engineering (human factors engineering) process permits the manufacturer to assess and mitigate risks associated with correct use and use errors, i.e., normal use. It can be used to identify but does not assess or mitigate risks associated with abnormal use. This first edition of IEC 62366-1, together with the first edition of IEC 62366-2 (not published yet), cancels and replaces the first edition of IEC 62366 published in 2007 and its Amendment 1:2014. Part 1 has been updated to		

include contemporary concepts of usability engineering, while also streamlining the process. It strengthens links to ISO 14971:2007 and the related methods of risk management as applied to safety related aspects of medical device user interfaces. Part 2, once published, will contain tutorial information to assist manufactures in complying with Part 1, as well as offering more detailed descriptions of usability engineering methods that can be applied more generally to medical devices that go beyond safety-related aspects of medical device user interfaces.		
IEC 60601-1-6	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	WP2, WP3, WP7, WP9
Description: IEC 60601-1-6:2010 specifies a process for a manufacturer to analyse, specify, design, verify and validate usability, as it relates to basic safety and essential performance of medical electrical equipment. This usability engineering process assesses and mitigates risks caused by usability problems associated with correct use and use errors, i.e., normal use. It can be used to identify but does not assess or mitigate risks associated with abnormal use. If the usability engineering process detailed in this collateral standard has been complied with and the acceptance criteria documented in the usability validation plan have been met (see 5.9 of IEC 62366:2007), then the residual risks, as defined in ISO 14971, associated with usability of me equipment are presumed to be acceptable, unless there is objective evidence to the contrary (see 4.1.2 of IEC 62366:2007). The object of this collateral standard is to specify general requirements that are in addition to those of the general standard and to serve as the basis for specific standards.		

3.1.2 Robots for touch

Number	Title	Relevant for WP
ISO 13482:2014	Robots and robotic devices — Safety requirements for personal care robots	WP2, WP3, WP5, WP6, WP7
Description: This International Standard specifies requirements and guidelines for the inherently safe design, protective measures, and information for use of personal care robots, in particular the following three types of personal care robots: mobile servant robot; physical assistant robot; person carrier robot. These robots typically perform tasks to improve the quality of life of intended users, irrespective of age or capability. This International Standard describes hazards associated with the use of these robots, and provides requirements to eliminate, or reduce, the risks associated with these hazards to an acceptable level. This International Standard covers human-robot physical contact applications. This International Standard presents significant hazards and describes how to deal with them for each personal care robot type. This International Standard covers robotic devices used in personal care applications, which are treated as personal care robots. This International Standard is limited to earthbound robots. This International standard does not apply to: robots		

travelling faster than 20 km/h; robot toys; water-borne robots and flying robots; industrial robots, which are covered in ISO 10218 robots as medical devices; military or public force application robots. The safety principles established in this International Standard can be useful for these robots listed above. The scope of this International Standard is limited primarily to human care related hazards but, where appropriate, it includes domestic animals or property (defined as safety-related objects), when the personal care robot is properly installed and maintained and used for its intended purpose or under conditions which can reasonably be foreseen. This International Standard is not applicable to robots manufactured prior to its publication date. This International Standard deals with all significant hazards, hazardous situations or hazardous events as described in Annex A. Attention is drawn to the fact that for hazards related to impact (e.g. due to a collision) no exhaustive and internationally recognised data (e.g. pain or injury limits) exist at the time of publication of this International Standard.		
EN 60601-1:2006	Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance	WP2, WP3, WP5, WP6, WP7
The general standard IEC 60601-1 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - gives general requirements of the series of standards. 60601 is a widely accepted benchmark for medical electrical equipment and compliance with IEC60601-1 has become a requirement for the commercialisation of electrical medical equipment in many countries. Many companies view compliance with IEC 60601-1 as a requirement for most markets. This standard does not assure effectiveness of a medical device. In the US, evidence of effectiveness is required by the FDA and confirmed through either a Premarket Approval (PMA) or similarity to a predicate device via a 510(k) Premarket Notification.		
EN ISO 9241-960:2017	Ergonomics of human-system interaction - Part 960: Framework and guidance for gesture interactions (ISO 9241-960:2017)	WP2, WP3, WP5, WP6, WP7
Description: Selection or creation of the gestures to be used in a gesture interface is guided by this standard. It addresses the usability of gestures and provides information on the design of gestures, the process and relevant parameters. In addition, the standard provides guidance on how gestures should be documented. The standard is concerned with the gestures expressed by a human and is not concerned with the system response generated when users are performing these gestures.		
IEC/TR 60601-4-1:2017	Medical electrical equipment — Part 4-1: Guidance and interpretation — Medical electrical equipment and	WP2, WP3, WP5, WP6, WP7

	medical electrical systems employing a degree of autonomy	
Description: IEC TR 60601-4-1:2017(E) is intended to help a manufacturer through the key decisions and steps to be taken to perform a detailed risk management and usability engineering processes for medical electrical equipment or a medical electrical system, hereafter referred to as MEE or MES, employing a degree of autonomy (DOA). This document provides a definition of DOA of MEE or MES and a medical robot, and provides guidance on: methodologies to perform the risk management process and usability engineering for an MEE or MES with a DOA; considerations of basic safety and essential performance for an MEE and MES with a DOA; and identifying the use of DOA, and similar concepts in existing ISO/IEC standards dealing with MEE or MES with the goal to facilitate alignment of standards by consistent use of the concept of DOA; and distinguishing between medical robots, and other MEE and MES. Unless specified otherwise, this document considers MEE and MES together. The manufacturer of an MEE or MES with a DOA is expected to design and manufacture an MEE or MES that fulfils its intended use and does not have unacceptable risk throughout its life cycle. This document provides guidance to help the manufacturer in complying with the requirements of IEC 60601-1:2005 and IEC 60601-1:2005/AMD1:2012 for MEE and MES with DOA. The document is also intended as guidance for future standard writers. There are no prerequisites to this document.		

3.1.3 User friendliness or ease of use and ergonomics

Number	Title	Relevant for WP
ISO/IEC 40500	Information technology -- W3C Web Content Accessibility Guidelines (WCAG) 2.0	WP2, WP7
Description: ISO/IEC 40500:2012 [Web Content Accessibility Guidelines (WCAG) 2.0] covers a wide range of recommendations for making Web content more accessible. Following these guidelines will make content accessible to a wider range of people with disabilities, including blindness and low vision, deafness and hearing loss, learning disabilities, cognitive limitations, limited movement, speech disabilities, photosensitivity and combinations of these. Following these guidelines will also often make your Web content more usable to users in general. WCAG 2.0 success criteria are written as testable statements that are not technology specific. Guidance about satisfying the success criteria in specific technologies, as well as general information about interpreting the success criteria, is provided in separate documents. An overview of WCAG 2.0, the WCAG 2.0 standard, technical and education material supporting implementation of WCAG 2.0, and information on translating WCAG 2.0, are freely available from Web Content Accessibility Guidelines (WCAG) Overview. WCAG 2.0 were drafted by W3C.		

ISO 20282-1	Ease of operation of everyday products -- Part 1: Design requirements for context of use and user characteristics	WP2, WP 7
Description: This part of ISO 20282 provides requirements and recommendations for the design of easy-to-operate everyday products, where ease of operation addresses a subset of the concept of usability concerned with the user interface by taking account of the relevant user characteristics and the context of use. This part of ISO 20282 is intended to be used in the development of everyday products, for which it defines ease of operation, explains which aspects of the context of use are relevant, and describes the characteristics of the intended user population that may influence usability. The intended users of this part of ISO 20282 are usability specialists, ergonomists, product designers, interaction designers, product manufacturers and others involved in the design and development of everyday products. This part of ISO 20282 is applicable to mechanical and/or electrical products with an interface that a user can operate directly or remotely to gain access to the functions provided. These products fall into at least one of the following categories: consumer products intended for some or all of the general public which are bought, rented or used, and which may be owned by individuals, public organisations, or private companies; consumer products intended to be acquired and used by an individual for personal rather than professional use (e.g. alarm clocks, electric kettles, telephones, electric drills); walk-up-and-use products that provide a service to the general public (such as ticket-vending machines, photocopying machines, fitness equipment); products used in a work environment, but not as part of professional activities (e.g. a coffee machine in an office); products including software that supports the main goals of use of the product (e.g. a CD player). This part of ISO 20282 is not applicable to the following: purely physical products without an interactive user interface (such as a jug or a hammer); products where appearance or fashion is the main goal (such as a watch with no markings); products requiring specialist training, specific skills and/or professional knowledge (such as a musical instrument or a car); standalone software products; products intended to be used for professional activities only. **NOTE 1: Some products include elements within the scope of this part of ISO 20282 and at the same time those that are not. For example, tasks relating to the use of a public internet access terminal such as switching that terminal on and off are within the scope of this part of ISO 20282, whereas tasks relating to the general use of the internet from the terminal are not.** **NOTE 2: This part of ISO 20282 can be used in conjunction with ISO 13407, which describes how to take account of wider aspects of usability within a human-centred design process.** **NOTE 3: Some of the guidance of this part of ISO 20282 could be applicable to other types of systems in everyday use.**		
ISO/TS 20282-2	Usability of consumer products and products for public use -- Part 2: Summative test method	WP2, WP 7

Description: This part of ISO/TS 20282 specifies a user-based summative test method for the measurement of the usability and/or accessibility of consumer products and products for public use (including walk-up-and-use products) for one or more specific user groups. This test method treats accessibility as a special case of usability where the users taking part in the test represent the extremes of the range of characteristics and capabilities within the general user population. When the test method refers to usability, the method can also be used to test accessibility (unless otherwise specified). This test method is for use when valid and reliable measures of effectiveness, efficiency, and satisfaction are needed.

NOTE 1: Products for public use include walk-up-and-use products that provide a service to the public. The test method can also be used to assess the usability and/or accessibility of achieving the goals of unpacking, installing, and setting up a consumer product. This part of ISO/TS 20282 is intended to be used for testing the usability and/or accessibility of products when it is possible to identify typical contexts of use that are representative of the use of the product(s), it is possible to identify the criteria for the successful achievement of the users' goal, and there are a limited number of goals being tested at the same time. While the test method is intended to cover consumer products and products for public use, it can also be used to test other products, systems, and services with the characteristics described above. If use of a product involves interaction with inputs, outputs, or environments that are highly variable and/or complex with variability or complexity that cannot be categorised in well-defined subsets, it is outside the scope as it would not be possible to obtain reliable results. See Annex A for examples of products and goals that are within the scope of this part of ISO/TS 20282.

EXAMPLE The method could be applied to an office photocopier, a website selling books or train tickets, or a legal advice service. The method would not be appropriate for a complex ecommerce website, a word processor, or a bicycle. The method is primarily intended for use for assessing completed versions of products but could also be used for internal purposes during development to judge, assess, and communicate the usability and/or accessibility of functional prototype versions. The results of the summative test method can be used for the following purposes:

- **to estimate the probability of achieving target values of effectiveness, efficiency, and satisfaction in actual use;**
- **to publish information about the usability and/or accessibility of a product;**
- **to compare the usability and/or accessibility of several products;**
- **to compare the results with a usability and/or accessibility requirements specification;**
- **to support procurement.**

NOTE 2: Annex H lists the information to be included when specifying the procedure used to test whether the usability and/or accessibility requirements (Annex G) have been met. The intended users of this part of ISO/TS 20282 are people with expertise in the design and management of testing usability and/or accessibility, working within or on behalf of manufacturers, suppliers, purchasing organisations, or third parties (such as test organisations or consumer organisations).

EN ISO 9241-20	Ergonomics of human-system interaction - Part 20: Accessibility guidelines for information/communication technology (ICT) equipment and services (ISO 9241-20:2008)	WP2, WP7
ISO 9241-20:2008 is intended for use by those responsible for planning, designing, developing, acquiring, and evaluating information/communication technology (ICT) equipment and services. It provides guidelines for improving the accessibility of ICT equipment and services such that they will have wider accessibility for use at work, in the home, and in mobile and public environments. It covers issues associated with the design of equipment and services for people with a wide range of sensory, physical and cognitive abilities, including those who are temporarily disabled, and the elderly.		
EN ISO 9241-220	Ergonomics of human-computer interaction — Part 220: Processes for enabling, executing and assessing human-centred design within organisations	WP2, WP7
Description: This International Standard specifies the processes by which human-centred design is achieved throughout the lifecycle of interactive systems (including products and services). It is also applicable to some noninteractive products, systems or environments intended for human use. These human-centred process (HCP) descriptions are for use in the specification, assessment and improvement of HCPs used in system development and operation. They can also provide the basis for professional development and certification. The processes support achievement of the overall objective of human-centred design when using a system: usability, accessibility, freedom from risk related to or arising from human use, and user experience (referred to as value-in-use). **NOTE 1: Human-centred design aims to make interactive systems more usable with potential benefits including improved productivity, enhanced user well-being, avoidance of stress, increased accessibility and reduced risk of harm. Ergonomics shares these objectives but is used beyond the domain of design, for example in the forensic analysis of the causes of accidents and in the generation of data and methods of measurement. The description of processes in this International Standard provides a basis for those planning and carrying out human-centred design activities within an organisation, and in the execution of projects. In addition, it can provide the basis for those who wish to improve the performance of human-centred design activities within their own organisation or in an organisation supplying systems or services. The guidance in this International Standard is not applicable to an organisational re-design, although its application might identify the necessity for re-design.** **NOTE 2: ISO 9241-2 and ISO TS 18152 address organisational design in more detail. This International Standard does not prescribe specific methods. The processes described in ISO 9241-220, can be implemented using a range of methods (such as those described in ISO/TR 16982). ISO 9241-210 specifies the approaches to human-**		

centred design to be used by project managers, while this International Standard is intended to be used by those performing and supporting human-centred design. These processes can be implemented according to the needs of the specific project and/or organisation. This International Standard specifies the purposes, outcomes, activities and work products for each process. Cross references are made to other parts of the ISO 9241 series that address the design and/or evaluation of components of an interactive system or its environment (see normative Annex B).		
EN ISO 9241-171	Ergonomics of human-system interaction - Part 171: Guidance on software accessibility (ISO 9241-171:2008)	WP2, WP7
Description: This part of ISO 9241 provides ergonomics guidance and specifications for the design of accessible software for use at work, in the home, in education and in public places. It covers issues associated with designing accessible software for people with the widest range of physical, sensory and cognitive abilities, including those who are temporarily disabled, and the elderly. It addresses software considerations for accessibility that complement general design for usability as addressed by ISO 9241-110, ISO 9241-11 to ISO 9241-17, ISO 14915 and ISO 13407. This part of ISO 9241 is applicable to the accessibility of interactive systems. It addresses a wide range of software (e.g. office, Web, learning support and library systems). It promotes the increased usability of systems for a wider range of users. While it does not cover the behaviour of, or requirements for, assistive technologies (including assistive software), it does address the use of assistive technologies as an integrated component of interactive systems. It is intended for use by those responsible for the specification, design, development, evaluation and procurement of software platforms and software applications.		
CEN ISO/TR 22411	Ergonomics data and guidelines for the application of ISO/IEC Guide 71 to products and services to address the needs of older persons and persons with disabilities	WP2, WP7
Description: ISO/TR 22411:2008 presents ergonomics data and guidelines for applying ISO/IEC Guide 71 in addressing the needs of older persons and persons with disabilities in standards development. It provides ergonomics data and knowledge about human abilities — sensory, physical and cognitive — and allergies, as well as guidance on the accessible design of products, services and environments.		
EN ISO 28802	Ergonomics of the physical environment - Assessment of environments by means of an environmental survey involving physical measurements of the environment and subjective	WP2, WP7

	responses of people (ISO 28802:2012)	
Description: The aim of the standard is to provide a standard environmental survey method for the assessment of the comfort and wellbeing of occupants of indoor and outdoor environments. It is not restricted to any environment but provides the general principles that allow assessment and evaluation. The standard applies to build environments as well as to other indoor environments, vehicle environments and outdoor environments. There may be specific features of certain types of environments that have to be considered, however the general principles outlined in this standard will apply. The standard applies to all occupants of environments who can be considered to provide valid responses to an environmental survey. The standard presents the principles of conducting an environmental survey to assess the comfort and wellbeing of people in environments. It involves guidance on the design of the survey as well as guidance on environmental measurements to quantify the environment and subjective assessment methods to quantify the occupants' responses to that environment. This standard is not restricted to specific environmental components. It includes assessment of thermal environments, the acoustic environment, lighting, air quality and other environmental factors that could be considered to influence the comfort and wellbeing of the occupants of an environment. This standard is a basic ergonomics standard which can contribute to the development of standards concerned with specific environments such as those found in buildings for example. The standard applies where ethical considerations and acceptable practices involving people have been carried out. This standard is intended to be used by people involved in the general assessment and evaluation of physical environments. It includes general ergonomics practitioners as well as those who develop standards and guidelines for specific applications.		
EN ISO 28803	Ergonomics of the physical environment - Application of international standards to people with special requirements (ISO 28803:2012)	WP2, WP7
Description: This international standard provides guidance to people who use and apply international standards concerned with the Ergonomics of the physical environment. They include people who are involved in environmental design and assessment. This international standard provides guidance on the application of existing international standards for people with special requirements. That is for those people who would be considered to be beyond the scope of existing standards concerned with the ergonomics of the physical environment. The standard has been produced according to the principles provided in ISO/IEC Guide 71 and the data provided in ISO TR 22411. The standard is not a database of the characteristics of people with special requirements. It uses data from the basic standard ISO TR 22411 to provide methods and criteria that will provide accessible environments for people with special requirements. The standard is not restricted to any specific environment but provides the general principles that allow assessment and evaluation. The standard applies to build environments as well as to other indoor environments, vehicle environments and outdoor environments. There may be specific features of certain types of environments that have to be taken into account, however the general principles outlined in this standard will apply. The		

standard applies to all occupants of environments who can be considered to have special requirements. This will depend upon context and can, for example, include babies, infants, males or females, people with disabilities, the effects of age, people who are ill and so on. A person may have a special requirement in one type of environment but not in another. The standard is based upon the principle of accessible design and provides a method for predicting the consequences (in terms of environmental comfort for example) for people with special requirements.		
CEN ISO/TR 22411	Ergonomics data and guidelines for the application of ISO/IEC Guide 71 to products and services to address the needs of older persons and persons with disabilities (ISO/TR 22411:2008)	WP2, WP7
Description: ISO/TR 22411:2008 presents ergonomics data and guidelines for applying ISO/IEC Guide 71 in addressing the needs of older persons and persons with disabilities in standards development. It provides ergonomics data and knowledge about human abilities — sensory, physical and cognitive — and allergies, as well as guidance on the accessible design of products, services and environments.		
ISO 24504	Ergonomics - Accessible design - Sound pressure levels of spoken announcements for products and public address systems	WP2, WP7
Description: This International Standard specifies methods to determine an appropriate sound pressure level range for spoken announcements in environments where ambient noise is less than 80 dB. The specified method follows the concepts of ISO/IEC Guide 71 and includes consideration of older persons with decreased hearing ability to determine sound pressure levels of spoken announcements. The spoken speech levels that are specified in this International Standard are for products and public-address systems. To improve the accessibility and usability of products, spoken announcements shall be not only audible but also presented at comfortable speech levels. The target products that present spoken announcements are consumer products such as electronic home appliances, information and communication technology services, and products providing services for general users in public facilities indoors and outdoors such as train stations, airports, meeting rooms, amusement parks, and fairs. This International Standard is not applicable to products providing private information such as automated teller machines in public spaces. This International Standard is applicable when a loudspeaker producing a spoken announcement is located a short distance from the user in an environment where the sound pressure level with a standard frequency weighting A of ambient noise does not exceed 80 dB. This International Standard is applicable to spoken announcements that are audible to persons with normal hearing for their age when presented by a target product under quiet and anechoic conditions. This International Standard is applicable for both recorded voice and synthetic speech announcements. This International Standard		

does not specify sound pressure levels of spoken announcements for systems with automatic sound pressure level control to compensate for fluctuating ambient noise levels. This International Standard is not applicable to spoken announcements heard through headphones or earphones, or to spoken announcements heard with the ear close to the speech sound source, such as in ear speakers specified in IEC 60268-7. This International Standard considers only the audibility of speech and not the process of speech understanding. This International Standard does not specify the sound pressure levels of spoken announcements presented in emergency situations such as signals for fire alarms, gas leakage, and crime prevention; those are covered in ISO 7240-16 and ISO 7240-19. This International Standard does not specify the sound pressure levels of spoken announcements in automobiles; those are covered in ISO 15006. **NOTE 1: A spoken announcement presented in a repetitive manner from a product such as electronic home appliance is presumed to be heard as an auditory sign but not as a message and is therefore usable with a lower sound pressure level of the spoken announcement than this International Standard specifies.** **NOTE 2: It is known that the word recognition performance of native speakers of the language of the announcement is better than that of non-native speakers.**		
ISO 24500	Ergonomics - Accessible design - Auditory signals for consumer products	WP2, WP7
Description: This International Standard specifies the auditory signals used as a means of feedback for operations or conditions of consumer products when used by a person with or without visual or auditory impairment. It is intended to be applied as appropriate to such products depending on the product type and its conditions of use. It is applicable to auditory signals of a fixed frequency used in general applications (also called "beep sounds"), but not to variable frequency or melodic sounds. It does not specify fire or gas leak alarm sounds or crime prevention alarm sounds (determined by other laws and regulations), electronic chimes, voice guides or other sounds specific to communication instruments such as telephones; nor is it applicable to auditory danger signals for public or work areas (covered in ISO 7731, ISO 8201, and ISO 11429). It is not applicable to machines and equipment used for professional work; nor does it specify the sound pressure levels of auditory signals from the consumer products. **NOTE: For the determination of these levels, taking into consideration accessible design, see ISO 24501.**		
ISO 24501	Ergonomics - Accessible design - Sound pressure levels of auditory signals for consumer products	WP2, WP7
Description: This International Standard specifies methods for determining the sound pressure level range of auditory signals so that the users of consumer products, including people with age-related hearing loss, can hear the signal properly in the presence of interfering sounds. Auditory signals, in this International Standard, refer to sounds with a fixed frequency (also called beep sounds) and do not include variable frequency sounds, melodic sounds, or voice guides. This International Standard is applicable to auditory signals which are heard at an		

approximate maximum distance of 4 m from the product, if no physical barrier exists between the product and the user. It is not applicable to auditory signals heard through a head receiver or earphones, or to those heard with the ear located very near to the sound source because of the interference of the head with sound propagation. This International Standard does not specify the sound pressure level of auditory signals regulated by other statutes, such as those for fire alarms, gas leakages and crime prevention, nor does it specify auditory signals related to a communication tool such as telephones. This International Standard does not specify auditory danger signals for public or work areas which are covered in ISO 7731, ISO 8201, and ISO 11429.		
ISO 24502	Ergonomics - Accessible design - Specification of age-related luminance contrast for coloured light	WP2, WP7
Description: This International Standard specifies the age-related luminance contrast of any two lights of different colour seen by a person at any age, by considering the age-related change of spectral luminous efficiency of the eye. This International Standard provides a basic method of calculation that can be applied to the design of lighting, visual signs and displays. It applies to light, self-luminous or reflected, in visual signs and displays seen under moderately bright conditions called photopic vision and whose spectral radiance is known or measurable. It does not apply to light seen under darker conditions called mesopic or scotopic vision. This International Standard specifies the luminance contrast for people aged from 10 to 79 years who have had no medical treatment or surgery on their eyes that may affect their spectral luminous efficiency. This International Standard does not apply to visual signs and displays seen by people with colour defects whose spectral luminous efficiency is different from those with normal colour vision, nor those seen by people with low vision.		
ISO 20282-1	Ease of operation of everyday products -- Part 1: Design requirements for context of use and user characteristics	WP2, WP7
Description: ISO 20282-1:2006 provides requirements and recommendations for the design of easy-to-operate everyday products, where ease of operation addresses a subset of the concept of usability concerned with the user interface by taking account of the relevant user characteristics and the context of use. ISO 20282-1:2006 is intended to be used in the development of everyday products, for which it defines ease of operation, explains which aspects of the context of use are relevant, and describes the characteristics of the intended user population that may influence usability. The intended users of this part of ISO 20282-1:2006 are usability specialists, ergonomists, product designers, interaction designers, product manufacturers and others involved in the design and development of everyday products. ISO 20282-1:2006 is applicable to mechanical and/or electrical products with an interface that a user can operate directly or remotely to gain access to the functions provided. These products fall into at least one of the following categories: consumer products intended for some or all of the general public which are bought, rented or used, and which may be owned by individuals, public organisations, or private companies; consumer products intended to be acquired and used by an individual for personal		

rather than professional use (e.g. alarm clocks, electric kettles, telephones, electric drills); walk-up-and-use products that provide a service to the general public (such as ticket-vending machines, photocopying machines, fitness equipment); products used in a work environment, but not as part of professional activities (e.g. a coffee machine in an office); products including software that supports the main goals of use of the product (e.g. a CD player). This part of ISO 20282 is not applicable to the following: purely physical products without an interactive user interface (such as a jug or a hammer); products where appearance or fashion is the main goal (such as a watch with no markings); products requiring specialist training, specific skills and/or professional knowledge (such as a musical instrument or a car); standalone software products; products intended to be used for professional activities only.		
ISO/TS 20282-2	Usability of consumer products and products for public use -- Part 2: Summative test method	WP2, WP7
Description: ISO/TS 20282:2013 specifies a user-based summative test method for the measurement of the usability and/or accessibility of consumer products and products for public use (including walk-up-and-use products) for one or more specific user groups. This test method treats accessibility as a special case of usability where the users taking part in the test represent the extremes of the range of characteristics and capabilities within the general user population. When the test method refers to usability, the method can also be used to test accessibility (unless otherwise specified).		

3.1.4 Health informatics

The size and complexity of the health informatics systems in use today leads to many general issues from other standardisation committees being incorporated into the healthcare sector. The issues, for example, relate to business architecture, security, social media, cloud applications, open service architecture and out licensing. Part of this is also relevant to welfare technology.

Number	Title	Relevant for WP
EN 1068:2005	Health informatics - Registration of coding systems	WP2, WP3, WP5, WP6, WP7
Description: This European Standard specifies a procedure for the registration of coding schemes used in health for any purpose. It also specifies the allocation of a unique Health Coding Scheme Designator to each registered coding scheme. A code value can thus be given an unambiguous meaning by association with an HCD. **The method by which a HCD and a code value are associated is not defined by this European Standard. The association is achieved in any manner appropriate to the syntax used.**		

This European Standard does not specify the coding schemes to be used in health, give guidance on their selection nor describe methods of representing information in coded form. **Coding schemes maintained by different Responsible Organisations may also be used in combinations. Such combinations can be considered as templates, and as such they lie outside the scope of the current document.**		
EN 1614:2006	Health informatics - Representation of dedicated kinds of property in laboratory medicine	WP2, WP3, WP5, WP6, WP7
Description: 1.1 Purpose **This European Standard provides a structure aiding the representation, e.g. systematic terms or coding systems, of dedicated kinds of property, including dedicated kinds of quantity, in laboratory medicine. The structure for representation is intended to facilitate the unambiguous communication of messages containing information about properties.** **1.2 Field of application** **This European Standard is applicable to all branches of laboratory medicine and other bodies offering laboratory analytic services. Examinations performed in the physician's office, at the bedside, or in the home are part of the laboratory medicine domain and thus this European Standard applies.** **1.3 Uses** **This structure for representation constitutes the essential basis for development of nomenclatures and coding systems intended for use in unambiguous and fully informative communication about properties, which fall within the field of application. Every such communication, including requests to and reports from clinical laboratories, and information retrieval for management reporting, research and reimbursement, will require additional information which are outside the scope of this European Standard.** **1.4 Limitations** **It should be emphasised that it is not the purpose of this European Standard to standardise the language used by health care practitioners in requesting or reporting clinical laboratory data. It may, however, be used as a guide by those who wish to adopt systematic terms for routine requesting and reporting of laboratory data.** **The syntax used for representing dedicated kinds-of-property is outside the scope of this European Standard, as are syntactic rules for the construction of codes in coding schemes.** **The purpose is not to standardise the presentation of properties or kinds-of-property in user interfaces of computer systems nor the presentation in printed documents.**		
EN 12251:2004	Health informatics - Secure User Identification for Health Care - Management	WP2, WP3, WP5, WP6, WP7

	and Security of Authentication by Passwords	
Description: This European standard is designed to improve the authentication of individual users of health care IT system, by strengthening the automatic software procedures associated with the management of user identifiers and passwords, without resorting to additional hardware facilities. This European standard applies to all information systems (hereafter called systems) within the health care environment that handle or store sensitive person identifiable health information, using passwords as the only means of authenticating the entered user identifier, i.e., verifying the claimed identity of a user. Systems that fall within the scope of this European standard include for example electronic patient record systems, patient administrative systems and laboratory systems, containing personal health information. This European standard does not apply to systems outside the health care environment. Neither does it apply to systems within the health care environment that use other means of identification and authentication, such as smart cards, biometric methods or other technical facilities.		
HL7 FHIR® SMART IG	HL7 FHIR® Implementation Guide: SMART Application Launch Framework, Release 1	WP2, WP3, WP5, WP 6WP6, WP7
Description: SMART App Launch Framework **SMART on FHIR provides reliable, secure authorisation for a variety of app architectures using the OAuth 2.0 standard.** **This profile is intended to be used by developers of apps that need to access FHIR resources by requesting access tokens from OAuth 2.0 compliant authorisation servers.**		
HL7 DAM for Medical Devices	HL7 Version 3 Domain Analysis Model: Detailed Clinical Models for Medical Devices, Release 1	WP2, WP3, WP5, WP6, WP7
Description: The objectives of this specification are to use a Domain Analysis Model (DAM) to specify reusable Detailed Clinical Models (DCM) to describe the information exchanged by medical devices with information systems. The DCMs are providing full semantics and structural description of measurements, settings, and other events reported by devices using standard clinical terminology. The analysis process associated with DAMs is used here to identify the context and content of DCMs as units of information intended to enable interoperability across devices and systems. **The DCMs and the associated DAM enable semantic interoperability for medical device measurements across devices and information system regardless of the information exchange standard used to move the information across (e.g. HL7 Version 2.x, HL7 CDA, etc.).** **A DAM is intended to improve communication of interoperability requirements and workflow automation between the business stakeholders, clinicians, vendors, and**		

integrators (both IT and clinical engineering) by involving the clinicians in the definition of information relevant for interoperability.		
EN 12264:2005	Health informatics - Categorial structures for systems of concepts	WP2, WP3, WP5, WP6, WP7
Description: The purpose of this European Standard is to establish the characteristics and the compliance rules required to synthetically describe, by its global categorial structure (a few high-level semantic categories and their organisation, instead of thousands of terms), the organisation and content of a terminological system in health, in order to support the exchange of meaningful health information between any terminological systems, including national and international classifications or coding systems for healthcare, and using different national languages within Europe. **The standard has been developed to allow the production of specific standards on categorial structures for specific healthcare subject fields and to ensure the compliance of computer-based health terminological systems from any subject field with the minimum requirements to support meaningful exchange of information.**		
EN 12435:2006	Health informatics - Expression of results of measurements in health sciences	WP2, WP3, WP5, WP6, WP7
Description: This document is intended for use by parties to the design, development, acquisition, use and monitoring of health-care related information and information systems. It provides a list of units of measurement to be used in representing values of measurable quantities in health sciences. **The International System of Units forms the basis for this EN. Units with their associated kinds-of-quantity are arranged in order of dimension in Tables 1, 2 and 4 (Clause 5), and in Annex A.** **Different kinds-of-quantity may apply to a given combination of component(s) and system. Often the different quantities are interconvertible and examples of such interconvertibility are given in Annex C.** **Tables of conversion factors (Annex A) are provided from units in current use to SI units or their multiples.** **To represent the result of a measurement (Clause 6), this EN addresses requirements for the following:** • **relational operator (Clause 4)** • **numerical value (Subclause 6.1)** • **uncertainty of measurement (Subclause 6.2; Annex D)** • **unit of measurement (Clause 5).** **This EN covers the requirements for representation of these data elements in displayed and printed form and provides an approach for support of languages in non-Roman alphabets (Clause 7).**		

The scope of this standard is limited to textual representation. Support is not provided for the display or printing of images or graphs. **This standard does not cover the requirements for expression of the results of measurements in speech, speech synthesis or handwriting. It does not cover the form and syntax of requests for clinical measurements, nor detailed aspects of data transmission. It refers the user to other CEN standards that address the detailed specification of the interchange format. It does not address the syntax for recording of natural-language statements about quantities, such as those used in recording information about drugs dispensed or about treatment of patients. It does not cover the units of financial quantities.**		
EN 14484:2003	Health informatics - International transfer of personal health data covered by the EU data protection directive - High level security policy	WP2, WP3, WP5, WP6, WP7
Description: This item will provide guidance on the data protection policy which should be implemented by organisations which are participants in international applications which involve transfer of person identifiable data across national borders and which require compliance with the EU Data Protection Directive.		
EN 14485:2003	Health informatics - Guidance for handling personal health data in international applications in the context of the EU data protection directive	WP2, WP3, WP5, WP6, WP7
Description: This European Standard provides guidance on data protection for those involved in international informatics applications which entail transmission of person health data from an EU Member State to a non-EU Member State. Its purpose is to assist in the application of the EU Directive on Data Protection [1].		
EN ISO 11073-10418:2014	Health informatics - Personal health device communication - Part 10418: Device specialization - International Normalized Ratio (INR) monitor (ISO/IEEE 11073-10418:2014, Corrected version 2014-05-01)	WP2, WP3, WP5, WP6, WP7
Description: The scope of this standard is to establish a normative definition of communication between personal telehealth International Normalized Ratio (INR) devices (agents) and managers (e.g. cell phones, personal computers, personal health appliances, set top boxes) in a manner that enables plug-and-play interoperability. It leverages work done in other ISO/IEEE 11073 standards including existing terminology, information profiles, application profile standards, and		

transport standards. It specifies the use of specific term codes, formats, and behaviours in telehealth environments restricting optionality in base frameworks in favour of interoperability. This standard defines a common core of functionality of personal physical activity monitors. In the context of personal health devices, INR monitoring refers to the measurement of the Prothrombin Time (PT) that is used to assess the level of anti-coagulant therapy and its presentation as the International Normalized Ratio compared to the Prothrombin Time of normal blood plasma. Applications of the INR monitor include the management of the therapeutic level of anti-coagulant used in the treatment of a variety of conditions. This standard provides the data modelling and its transport shim layer according to the ISO/IEEE11073-20601 standard and does not specify the measurement method.		
EN ISO 11073-10471:2011	Health Informatics - Personal health device communication - Part 10471: Device specialization - Independent living activity hub (ISO/IEEE 11073-10471:2010)	WP2, WP3, WP5, WP6, WP7
Description: Standardisation in the field of health informatics, to facilitate capture, interchange and use of health-related data, information, and knowledge to support and enable all aspects of the health system.		
EN ISO 11073-20601:2016	Health informatics - Personal health device communication - Part 20601: Application profile - Optimized exchange protocol (ISO/IEEE 11073-20601:2016, including Cor 1:2016)	WP2, WP3, WP5, WP6, WP7
EN ISO 12052:2017	Health informatics - Digital imaging and communication in medicine (DICOM) including workflow and data management (ISO 12052:2017)	WP2, WP3, WP5, WP6, WP7
Description: ISO 12052:2017, within the field of health informatics, addresses the exchange of digital images and information related to the production and management of those images, between both medical imaging equipment and systems concerned with the management and communication of that information. ISO 12052:2017 facilitates interoperability of medical imaging equipment by specifying: - for network communications, a set of protocols to be followed by devices claiming conformance to this document; - the syntax and semantics of Commands and associated information which can be exchanged using these protocols; - for media communication, a set of media storage services to be followed by devices claiming conformance to this document, as well as a File Format and a medical directory structure to facilitate access to the images and related		

information stored on interchange media; - information that is to be supplied with an implementation for which conformance to this document is claimed. ISO 12052:2017 does not specify: - the implementation details of any features of the DICOM standard on a device claiming conformance; - the overall set of features and functions to be expected from a system implemented by integrating a group of devices each claiming conformance to this document; - a testing/validation procedure to assess an implementation's conformance to this document. ISO 12052:2017 pertains to the field of medical informatics. Within that field, it addresses the exchange of digital information between medical imaging equipment and other systems. Because such equipment may interoperate with other medical devices and information systems, the scope of this document needs to overlap with other areas of medical informatics. However, this document does not address the full breadth of this field. ISO 12052:2017 has been developed with an emphasis on diagnostic medical imaging as practiced in radiology, cardiology, pathology, dentistry, ophthalmology and related disciplines, and image-based therapies such as interventional radiology, radiotherapy and surgery. However, it is also applicable to a wide range of image and non-image related information exchanged in clinical, research, veterinary, and other medical environments. ISO 12052:2017 facilitates interoperability of systems claiming conformance in a multi-vendor environment, but does not, by itself, guarantee interoperability.		
EN ISO 12967-1:2011	Health informatics - Service architecture - Part 1: Enterprise viewpoint (ISO 12967-1:2009)	WP2, WP3, WP5, WP6, WP7
Description: This part of ISO 12967 provides guidance for the description, planning and development of new systems, as well as for the integration of existing information systems, both within one enterprise and across different healthcare organisations, through an architecture integrating the common data and business logic into a specific architectural layer (i.e. the middleware), distinct from individual applications and accessible throughout the whole information system through services. This part of ISO 12967 is also independent from, and does not imply either explicitly or implicitly, any specific technological solution or product for its deployment. Accordingly, the formalisation of the architecture according to two lower levels of the ODP reference model, the engineering and technology viewpoints, is outside the scope of this part. The language and notations used here for specifying the architecture are based on UML (Unified Modelling Language) complemented by case studies and other paradigms widely utilised by other standards in health informatics. The level of the specification is complete and non-ambiguous enough to allow its implementation into the specific physical and technological scenarios adopted by the various healthcare organisations and vendors. For this exercise, it is recommended to follow the methodology formalised by the engineering and Technology viewpoints of the RM ODP Reference model1).		
EN ISO 12967-2:2011	Health informatics - Service architecture - Part 2: Information viewpoint (ISO 12967-2:2009)	WP2, WP3, WP5, WP6, WP7
Description: This part of ISO 12967 specifies the fundamental characteristics of the information model to be implemented by a specific architectural layer (i.e. the middleware) of the information system to provide a comprehensive and integrated		

storage of the common enterprise data and to support the fundamental business processes of the healthcare organisation, as defined in ISO 12967-1. The information model is specified without any explicit or implicit assumption on the physical technologies, tools or solutions to be adopted for its physical implementation in the various target scenarios. The specification is nevertheless formal, complete and non-ambiguous enough to allow implementers to derive an efficient design of the system in the specific technological environment that will be selected for the physical implementation. This specification does not aim at representing a fixed, complete, specification of all possible data that can be necessary for any requirement of any healthcare enterprise. It specifies only a set of characteristics, in terms of overall organisation and individual information objects, identified as fundamental and common to all healthcare organisations, and that is satisfied by the information model implemented by the middleware. Preserving consistency with the provisions of this part of ISO 12967, physical implementations allow extensions to the standard information model in order to support additional and local requirements. Extensions include both the definition of additional attributes in the objects of the standard model, and the implementation of entirely new objects. Also this standard specification is extensible over time according to the evolution of the applicable standardisation initiatives. The specification of extensions is carried out according to the methodology defined in ISO 12967-1:2009, Clause 7, "Methodology for extensions".		
EN ISO 12967-3:2011	Health informatics - Service architecture - Part 3: Computational viewpoint (ISO 12967-3:2009)	WP2, WP3, WP5, WP6, WP7
Description: HISA specifies fundamental requirements for 'information infrastructure' and healthcare specific middleware services. This part of ISO 12967 specifies the fundamental characteristics of the computational model to be implemented by a specific architectural layer of the information system (i.e. the middleware) to provide a comprehensive and integrated interface to the common enterprise information and to support the fundamental business processes of the healthcare organisation, as defined in ISO 12967-1. The computational model is specified without any explicit or implicit assumption about the physical technologies, tools or solutions to be adopted for its physical implementation in the various target scenarios. The specification is nevertheless formal, complete and non-ambiguous enough to allow implementers to derive an efficient design of the system in the specific technological environment which will be selected for the physical implementation. The computational model provides the basis for ensuring consistency between different engineering and technology specifications (including programming languages and communication mechanisms) since they must be consistent with the same computational object model. This consistency allows open inter-working and portability of components in the resulting implementation. This specification does not aim at representing a fixed, complete, specification of all possible interfaces that may be necessary for any requirement of any healthcare enterprise. It specifies only a set of characteristics - in terms of overall organisation and individual computational objects, identified as fundamental and common to all healthcare organisations, and that are satisfied by the computational model implemented by the middleware. Preserving consistency with the provisions of this part of ISO 12967, physical implementations shall allow extensions to the standard computational model to support additional and local requirements.		

EN ISO 13606-1:2019	Health informatics - Electronic health record communication - Part 1: Reference model (ISO 13606-1:2019)	WP2, WP3, WP5, WP6, WP7
Description: This document specifies a means for communicating part or all of the electronic health record (EHR) of one or more identified subjects of care between EHR systems, or between EHR systems and a centralised EHR data repository. It can also be used for EHR communication between an EHR system or repository and clinical applications or middleware components (such as decision support components), or personal health applications and devices, that need to access or provide EHR data, or as the representation of EHR data within a distributed (federated) record system. This document will predominantly be used to support the direct care given to identifiable individuals or self-care by individuals themselves, or to support population monitoring systems such as disease registries and public health surveillance. Uses of health records for other purposes such as teaching, clinical audit, administration and reporting, service management, research and epidemiology, which often require anonymisation or aggregation of individual records, are not the focus of this document but such secondary uses might also find the document useful. This document is not intended to specify the internal architecture or database design of EHR systems.		
ISO 21091:2013	Health informatics -- Directory services for healthcare providers, subjects of care and other entities	WP2, WP3, WP5, WP6, WP7
Description: This standard will define minimal specifications for directory services for health care using the X.500 framework. This standard provides the common directory information and services needed to support the secure exchange of health care information over public networks. This specification addresses the health services directory from a community and Health Information Exchange perspective in anticipation of supporting inter-enterprise, inter-jurisdiction, and international health care communications. Besides technical security measures that are discussed in other ISO standards, communication of health care data requires a reliable, accountable "chain of trust." To maintain this chain of trust within a public key infrastructure, users (relying parties) must be able to obtain current correct certificates and certificate status information through secure directory management. In addition to the support of security services such as access control and confidentiality, the standard shall provide specification for other aspects of communication, such as addresses and protocols of communication entities. This standard also supports directory services aiming to support identification of health professionals and organisations and the patients/consumers. The latter services include aspects sometimes referred to as master patient indices. This standard can be used to enable communications between organisations, devices, systems, technical actors, and services. The health care services directory will only support standard LDAP Client searches. Specific implementation guidance, search criteria and support are out of scope of this document.		

EN ISO 21090:2011	Health Informatics - Harmonized data types for information interchange (ISO 21090:2011)	WP4, WP6
Description: The standard provides a set of datatype definitions for representing and exchanging basic concepts that are commonly encountered in healthcare environments in support of information exchange in the healthcare environment; **- specifies a collection of healthcare-related datatypes suitable for use in a number of health-related information environments;** **- declares the semantics of these datatypes using the terminology, notations and datatypes defined in ISO/IEC 11404, thus extending the set of datatypes defined in that standard;** **- provides UML definitions of the same datatypes using the terminology, notation and types defined in Unified Modelling Language (UML) version 2.0;** **- specifies an XML (Extensible Mark-up Language) based representation of the datatypes.** **The requirements which underpin the scope reflect a mix of requirements gathered primarily from HL7 Version 3 and ISO/IEC 11404, and from CEN/TS 14796, ISO 13606 (all parts) and past ISO work on healthcare datatypes.** **ISO 21090:2011 can offer a practical and useful contribution to the internal design of health information systems but is primarily intended to be used when defining external interfaces or messages to support communication between them.**		
ISO 22857:2013	Health informatics — Guidelines on data protection to facilitate trans-border flows of personal health data	WP4, WP6
Description: This International Standard provides guidance on data protection requirements to facilitate the transfer of personal health data across national or jurisdictional borders. It does not require the harmonisation of existing national or jurisdictional standards, legislation or regulations. It is normative only in respect of international or trans-jurisdictional exchange of personal health data. However, it can be informative with respect to the protection of health information within national/jurisdictional boundaries and provide assistance to national or jurisdictional bodies involved in the development and implementation of data protection principles. This International Standard covers both the data protection principles that apply to international or trans-jurisdictional transfers and the security policy which an organisation adopts to ensure compliance with those principles. Where a multilateral treaty between a number of countries has been agreed (e.g. the EU Data Protection Directive), the terms of that treaty will take precedence. This International Standard aims to facilitate international and trans-jurisdictional health-related applications involving the transfer of personal health data. It seeks to provide the means by which health data relating to data subjects, such as patients, will be adequately protected when sent to, and processed in, another country/jurisdiction. This International Standard does not provide definitive legal		

advice but comprises guidance. When applying the guidance to a specific application, legal advice appropriate to that application can be sought. National privacy and data protection requirements vary substantially and can change relatively quickly. Whereas this International Standard in general encompasses the more stringent of international and national requirements it nevertheless comprises a minimum. Some countries/jurisdictions may have some more stringent and specific requirements.		
ISO 27789:2013	Health informatics -- Audit trails for electronic health records	WP2, WP3, WP5, WP6, WP7
Description: Electronic health records on an individual may reside in many different information systems within and across organisational or national boundaries. To keep track of all actions that involve records on an individual a common framework for audit trails is a prerequisite. ISO 27799 requires information systems containing personal health information to create a secure audit record each time a user accesses, creates, updates, or archives personal health information via the system. This audit record will, at a minimum, uniquely identify the user, uniquely identify the data subject (i.e., the patient), identify the function performed by the user (record creation, access, update, etc.), and its point in time. However, ISO 27799 does not specify the format and processes for these. Audit trails on electronic health records across different systems (including archives) need a comprehensive common framework to keep the complete set of personal health information auditable. This project will specify the minimum requirements in terms of what events and what data to include in the audit log. Minimum requirements for audit log management (e.g. retention periods) will also be given. Examples will be given of services for audit log management based on this standard.		
EN ISO 11239:2012	Health informatics -- Identification of medicinal products -- Data elements and structures for the unique identification and exchange of regulated information on pharmaceutical dose forms, units of presentation, routes of administration and packaging	WP2, WP3, WP5, WP6, WP7
The standard specifies: · **the structures and relationships between the data elements required for the exchange of information, which uniquely and with certainty identify pharmaceutical dose forms, units of presentation, routes of administration and packaging items related to medicinal products;** · **a mechanism for the association of translations of a single concept into different languages;** · **a mechanism for the versioning of the concepts in order to track their evolution;**		

· **rules to allow regional authorities to map existing regional terms to the terms created using ISO 11239:2012 in a harmonised and meaningful way.**		
EN ISO 11240:2012	Health informatics -- Identification of medicinal products -- Data elements and structures for the unique identification and exchange of units of measurement	WP2, WP3, WP5, WP6, WP7
The standard: • **specifies rules for the usage and coded representation of units of measurement for the purpose of exchanging information about quantitative medicinal product characteristics that require units of measurement (e.g. strength) in the human medicine domain;** • **establishes requirements for units in order to provide traceability to international metrological standards;** • **provides rules for the standardised and machine-readable documentation of quantitative composition and strength of medicinal products, specifically in the context of medicinal product identification;** • **defines the requirements for the representation of units of measurement in coded form;** • **provides structures and rules for mapping between different unit vocabularies and language translations to support the implementation of ISO 11240:2012, considering that existing systems, dictionaries and repositories use a variety of terms and codes for the representation of units.** **The scope of ISO 11240:2012 is limited to the representation of units of measurement for data interchange between computer applications.**		
EN ISO 11615:2017	Health informatics -- Identification of medicinal products -- Data elements and structures for the unique identification and exchange of regulated medicinal product information	WP2, WP3, WP5, WP6, WP7
Description: ISO 11615:2017 establishes definitions and concepts and describes data elements and their structural relationships, which are required for the unique identification and the detailed description of Medicinal Products. Taken together, the standards listed in the Introduction define, characterise and uniquely identify regulated Medicinal Products for human use during their entire life cycle, i.e. from development to authorisation, post-marketing and renewal or withdrawal from the market, where applicable. Furthermore, to support successful information exchange in relation to the unique identification and characterisation of Medicinal Products, the use of other normative IDMP messaging standards is included, which are to be applied in the context of ISO 11615:2017.		

EN ISO 11616:2017	Health informatics -- Identification of medicinal products -- Data elements and structures for the unique identification and exchange of regulated pharmaceutical product information	WP2, WP3, WP5, WP6, WP7
Description: ISO 11616:2017 is intended to provide specific levels of information relevant to the identification of a Medicinal Product or group of Medicinal Products. It defines the data elements, structures and relationships between data elements that are required for the exchange of regulated information, to uniquely identify pharmaceutical products. This identification is to be applied throughout the product lifecycle to support pharmacovigilance, regulatory and other activities worldwide. In addition, ISO 11616:2017 is essential to ensure that pharmaceutical product information is assembled in a structured format with transmission between a diverse set of stakeholders for both regulatory and clinical (e.g. e-prescribing, clinical decision support) purposes. This ensures interoperability and compatibility for both the sender and the recipient. ISO 11616:2017 is not intended to be a scientific classification for pharmaceutical products. Rather, it is a formal association of data elements categorised in prescribed combinations and uniquely identified when levelling degrees of information are incomplete. This allows for Medicinal Products to be unequivocally identified on a global level. References to other normative IDMP and messaging standards for pharmaceutical product information are included in Clause 2, to be applied in the context of ISO 11616:2017. Medicinal products for veterinary use are out of scope of ISO 11616:2017.		
EN ISO 1828:2012	Health informatics - Categorial structure for terminological systems of surgical procedures (ISO 1828:2012)	WP2, WP3, WP5, WP6, WP7
Description: This European Standard specifies the characteristics of a categorial structure and the minimal domain constraints required for conformance, to support the exchange of meaningful surgical procedure information between different national terminologies of surgical procedures using different national languages within Europe. Categorial Structures supports interoperability by providing common frameworks with which to a) develop terminologies that can be related to each other and b) to analyse the properties of different terminologies to establish the relationship between them. This standard is applicable to: organisations involved with the development or maintenance of classifications and coding systems for medical procedures, namely for multipurpose coding systems on a national or international level organisations developing and maintaining software tools allowing natural clinical language expressions analysis, generation and mapping to the main existing classifications of surgical procedures. The standard has been developed for use as an integrated part of computer-based applications and for the electronic healthcare record. It would be of limited value for manual use. The standard itself is not suitable for or intended for use by, the individual clinician or hospital administrator. It is not the purpose of this standard to standardise the end user classification or to conflict with the concept systems embedded in national		

practice and languages. This standard is applicable to surgical procedures in all surgical disciplines.		
ISO 13119:2016	Health informatics -- Clinical knowledge resources – Metadata	WP2, WP3, WP5, WP6, WP7
Description: This standard defines a number of metadata elements that describe documents containing medical knowledge, primarily digital documents provided as web resources, accessible from databases or via file transfer, but can be applicable also to paper documents, e.g. articles in the medical literature. It is based on the ISO 15836:2003 Information and documentation- Metadata – The Dublin Core metadata element set. The metadata for these purposes are grouped into resource form, intended use, subject and scope, identification and source, and quality management system. The metadata should: •support unambiguous and international understanding of important aspects to describe a document, e.g. purpose, issuer, intended audience, legal status and scientific background; • be applicable to different kinds of digital documents e.g. recommendation from consensus of a professional group, regulation by a governmental authority, clinical trial protocol from a pharmaceutical company, scientific manuscript from a research group, advice to patients with a specific disease, review article; • be possible to present to human readers including health professionals as well as citizens/patients • be potentially usable for automatic processing e.g. to support search engines to restrict matches to documents of a certain type or quality level. The metadata here described is not intended to: • describe documents about a single patient, such as medical records; • describe details of the medical content of the document (but some idea of the content can be described via keywords or codes); • prescribe criteria for the quality of the document content.		
ISO/TS 22220:2011	Health informatics -- Identification of subjects of health care	WP2, WP3, WP5, WP6, WP7
Description: Standardisation in the field of health informatics, to facilitate capture, interchange and use of health-related data, information, and knowledge to support and enable all aspects of the health system.		
CEN/TS 15699:2009	Health informatics - Clinical knowledge resources – Metadata	WP2, WP3, WP5, WP6, WP7
Description: This Technical Specification defines a number of metadata elements that describe documents containing medical knowledge, primarily digital documents provided as web resources, accessible from databases or via file transfer, but can be applicable also to paper documents, e.g. articles in the medical literature. The metadata should: support unambiguous and international understanding of important aspects to describe a document e.g. purpose, issuer, intended audience, legal status and scientific background; be applicable to different kinds of digital documents e.g. recommendation from consensus of a professional group, regulation by a governmental authority, clinical trial protocol from a pharmaceutical company, scientific manuscript from a research group, advice to patients with a specific disease, review article; be possible to present to human readers including health professionals as well as citizens/patients be		

potentially usable for automatic processing e.g. to support search engines to restrict matches to documents of a certain type or quality level. The metadata here described is not intended to: describe documents about a single patient, such as medical records; describe details of the medical content of the document (but some idea of the content can be described via keywords or codes); prescribe criteria for the quality of the document content.		
EN ISO/HL7 10781:2015	Health Informatics - HL7 Electronic Health Records-System Functional Model, Release 2 (EHR FM) (ISO 10781:2015)	WP2, WP3, WP5, WP6, WP7
Description: ISO 10781:2015 provides a reference list of functions that may be present in an Electronic Health Record System (EHR-S). The function list is described from a user perspective with the intent to enable consistent expression of system functionality. This EHR-S Functional Model, through the creation of Functional Profiles for care settings and realms, enables a standardised description and common understanding of functions sought or available in a given setting (e.g. intensive care, cardiology, office practice in one country or primary care in another country).		
HL7 EHR-S FM Release 2.1	HL7 Electronic Health Record System Functional Model (EHR-S FM) Release 2.1	WP2, WP3, WP5, WP6, WP7
Description: Incremental update to the EHR System Functional Model (EHR-S FM), encompassing all the EHR functions and conformance criteria found in its predecessor Release 2, and incorporating: **1. Changes to the Record Infrastructure Section to accommodate three additional record lifecycle events (verify, encrypt, decrypt) and ensure compatibility with FHIR Core R4 Record Lifecycle Event Implementation Guide (2019) and recent updates to ISO 21089:2018, Trusted End-to-End Information Flows;** **2. Changes to the Glossary Section to support the full set of record lifecycle events (now 27 in total) and corresponding descriptions;** **3. Previously identified updates included in the EHR-S FM R2.01 errata version;** **4. Changes to the Conformance Chapter to align with characteristics and requirements of recent EHR-S FM R2 based Functional Profiles, including FPs developed for the US Meaningful Use (EHR Incentive) Programme, 2011/2014 and 2015 Editions;** **5. Domain analysis (models and artefacts) companion to EHR system development and implementation.** **Adding a header in the TI section on clinical model services (DCMs, CIMI models, FHIR, HL7 template) comparable to TI.4 Standard Terminology and Terminology Services.**		
ISO/HL7 16527:2016	Health informatics — HL7 Personal Health Record System Functional Model, Release 1 (PHRS FM	WP2, WP3, WP5, WP6, WP7

Description: ISO/HL7 16527 PHR-S FM:2016 defines a standardised model of the functions that may be present in PHR Systems.

It is beyond the scope of the PHR system to control the use (or intended use) of PHR data. On the contrary, it is within the scope of the PHR system to manage the authorisation of an individual (or other application). Those parties are then responsible for using the data for appropriate (or intended) purposes. The system manufacturers specify "intended and permitted use of PHR data" in their Terms of Service and Terms of Use agreements.

This Functional Model is not:

- **a messaging specification;**
- **an implementation specification;**
- **a conformance specification;**
- **a specification for the underlying PHR (i.e. the record itself);**
- **an exercise in creating a definition for a PHR;**
- **a conformance or conformance testing metric;**
- **a requirement specification for a single PHR system (see Annex D, Anticipated Uses).**

The information exchange enabled by the PHR-S supports the retrieval and population of clinical documents and summaries, minimum data sets, and other input/outputs.

EN ISO 18104	Health informatics - Categorial structures for representation of nursing diagnoses and nursing actions in terminological systems (ISO 18104:2014)	WP2, WP3, WP5, WP6, WP7

Description: ISO 18104:2014 specifies the characteristics of two categorial structures, with the overall aim of supporting interoperability in the exchange of meaningful information between information systems in respect of nursing diagnoses and nursing actions. Categorial structures for nursing diagnoses and nursing actions support interoperability by providing common frameworks with which to analyse the features of different terminologies, including those of other healthcare disciplines, and to establish the nature of the relationship between them, develop terminologies for representing nursing diagnoses and nursing actions, develop terminologies that are able to be related to each other, and establish relationships between terminology models, information models and ontologies in the nursing domain.

It is applicable to the following user groups: developers of terminologies that include nursing diagnosis and nursing action concepts; developers of categorial structures and terminologies for other healthcare domains, to support clarification of any relationship to or overlap with nursing concepts; developers of models for health information management systems such as electronic health records and decision support systems, to describe the expected content of terminological value domains for attributes and data elements in the information models; developers of

information systems that require an explicit system of concepts for internal organisation, data warehouse management or middleware services; developers of software for natural language processing, to facilitate harmonisation of their output with coding systems. **It is not intended for use by clinical nurses without health informatics expertise. However, it introduces categorial structures to assist those without health informatics expertise to contribute to its development, review, implementation and evaluation.** **Topics considered outside the scope of ISO 18104:2014 include complete categorial structures that would cover all the potential details that could appear in expressions of nursing diagnoses and nursing actions, a detailed terminology of nursing diagnoses or nursing actions, a "state model" for diagnoses or actions, for example, provisional diagnosis or absent diagnosis, planned action or action not to be done, diagnoses made and actions undertaken by nurses working in other professional roles, and knowledge relationships such as causal relationships between concepts.**		
EN ISO 13606-1	Health informatics -- Electronic health record communication -- Part 1: Reference model	WP2, WP3, WP5, WP6, WP7
Description: This document specifies a means for communicating part or all of the electronic health record (EHR) of one or more identified subjects of care between EHR systems, or between EHR systems and a centralised EHR data repository. It can also be used for EHR communication between an EHR system or repository and clinical applications or middleware components (such as decision support components), or personal health applications and devices, that need to access or provide EHR data, or as the representation of EHR data within a distributed (federated) record system. This document will predominantly be used to support the direct care given to identifiable individuals or self-care by individuals themselves, or to support population monitoring systems such as disease registries and public health surveillance. Uses of health records for other purposes such as teaching, clinical audit, administration and reporting, service management, research and epidemiology, which often require anonymisation or aggregation of individual records, are not the focus of this document but such secondary uses might also find the document useful. This Part 1 of the multipart series is an Information Viewpoint specification as defined by the Open Distributed Processing Reference model: Overview (ISO/IEC 10746-1). This document is not intended to specify the internal architecture or database design of EHR systems.		
ISO 13606-2	Health informatics -- Electronic health record communication -- Part 2: Archetype interchange specification	WP2, WP3, WP5, WP6, WP7
Description: This document specifies a means for communicating part or all the electronic health record (EHR) of one or more identified subjects of care between EHR systems, or between EHR systems and a centralised EHR data repository. It can also be used for EHR communication between an EHR system or repository and clinical applications or middleware components (such as decision support components) that need to access or provide EHR data, or as the representation of		

EHR data within a distributed (federated) record system. This document will predominantly be used to support the direct care given to identifiable individuals, or to support population monitoring systems such as disease registries and public health surveillance. Uses of health records for other purposes such as teaching, clinical audit, administration and reporting, service management, research and epidemiology, which often require anonymisation or aggregation of individual records, are not the focus of this standard series but such secondary uses might also find it useful. This document defines an Archetype Model to be used to represent Archetypes when communicated between repositories, and between archetype services. It defines an optional serialised representation, which may be used as an exchange format for communicating individual archetypes. Such communication might, for example, be between archetype libraries or between an archetype service and an EHR persistence or validation service.		
ISO/TS 13972	Health informatics — Detailed clinical models, characteristics and processes	WP2, WP3, WP5, WP6, WP7
Description: This Technical Specification: Describes requirements and recommended methods against which clinicians can gather, analyse and specify the clinical context, content, and structure of Detailed Clinical Models. Defines Detailed Clinical Models (DCMs) in terms of an underlying logical model. They are logical models of clinical concepts and can be used to define and to structure clinical information. Describes requirements and principles for DCMs, meta-data, versioning, content and context specification, data element specification and data element relationships, and provide guidance and examples. Specifies DCM governance principles to ensure conceptual integrity of all DCM attributes and logical model accuracy. Describes DCM development and the methodology principles for use that will support the production of quality DCMs to minimise risk and ensure patient safety. This Technical Specification is not applicable to: Details of the content of instances of Detailed Clinical Models. e.g. This Technical Specification will not specify the concrete data elements for the Glasgow Coma Scale, body height, and such (apart from some examples to explain the clauses). It will however give guidance on how to properly specify the clinical knowledge of Glasgow Coma Scale or body height, how to correctly identify, name and model the data elements for these clinical concepts, and how to give unique codes to each data element and, where possible, value set. In other words, it will explain the how to create instances, but not offer the instances themselves. Specifications of dynamic modelling, for example workflow. Specifications for modelling entire domains or aggregates of many Detailed Clinical Models such as complete assessment documents or discharge summaries. It will not specify DCM compositions.		
ISO TS 13131	Health informatics — Telehealth services — Quality planning guidelines	WP2, WP3, WP5, WP6, WP7
Description: A growing number of initiatives in various countries around the world, most of them small-scale, are described as telehealth or telemedicine or m-health projects. It is not yet clear when the term telehealth or telemedicine should be used to describe such initiatives, because these terms can be described and interpreted in different ways in the absence of a unifying concept. Telehealth is the use of information and communications technologies to deliver healthcare and transmit		

health information over both long and short distances. Telehealth is a form of care provision that extends the reach of care, reduces the need for care recipient or client travel and mobility, supports choice in healthcare service delivery, preventative care, individual self-care, and may also increase the efficiency of care. Currently telemedicine is seen as a providing a subset of a broader suite of telehealth services. Telehealth also includes ICT applications that support a wider set of activities including educational and administrative use. This Technical Specification provides advice and recommendations on how to develop quality objectives and guidelines for telehealth services that use information and communications technologies (ICTs) to deliver healthcare over both long and short distances by using a risk management process. The following key requirements are considered when developing quality objectives and guidelines for telehealth services: management of telehealth quality processes by the healthcare organisation; management of financial resources to support telehealth services; processes relating to people such as workforce planning, healthcare planning, and responsibilities; provision of infrastructure and facilities resources for telehealth services; management of information and technology resources used in telehealth services.		
ISO/TS 22789	Health informatics -- Conceptual framework for patient findings and problems in terminologies	WP2, WP3, WP5, WP6, WP7
Description: The purpose of this Technical Specification is to specify a categorial structure, within the subject field of patient findings and problems, by defining a set of common domain constraints for use within terminological systems including a classification, coding scheme, coding system, reference terminology and clinical terminology. Clinical findings are concepts that are recorded in clinical records and can describe any state observed directly or indirectly concerning a patient and their relationship with the environment. This Technical Specification is focused on a sub-population of these findings concerning descriptions of state (structure and function) directly related to the patient. This class of concepts includes: diseases, which may be defined as a state caused by a known or assumed pathological process impairing the normal physiological function and/or anatomical structure affecting all or part of a patient, where a specific pathological change is caused by a defined mechanism; findings of state or function (including normal findings) observed directly relating to a patient. This Technical Specification describes a concept system detailing a domain constraint of sanctioned characteristics each composed of a semantic link and an applicable characterising category. The potential uses for this conceptual framework are to: support developers of new terminology systems concerning patient findings and problems; support developers of new detailed content areas of existing terminology systems concerning patient findings and problems to ensure conformance; facilitate the representation of patient findings and problems using a standard core model in a manner suitable for computer processing; provide a conceptual framework for the generation of compositional concept representation of patient findings and problems; facilitate the mapping and improved semantic correspondence between different terminologies by proposing a core specification for patient findings and problems; provide a core model to describe the structure of patient findings and problems, and facilitate improved semantic correspondence with information models. **Target groups: The target groups for this Technical Specification are: developers of terminology systems concerning patient findings and problems; developers of**		

information systems that require a structured framework of concepts to facilitate implementation; IT specialists, analysts and epidemiologists who require common models of knowledge to facilitate analysis of current and legacy data from one or more information systems; clinicians and coders to provide greater consistency in structure and organisation when entering and retrieving data using one or more terminology systems; managers and administrative personnel in providing a benchmark by which to judge terminology solutions: as to whether the potential options will deliver compatibility with legacy data and future proofing to emerging terminology products. **Topics considered outside the scope: Topics considered outside the scope of this Technical Specification include: a comprehensive categorial structure for clinical findings; laboratory findings (including biochemical and histological results); signal findings (including the output from imaging and electrophysiological tests); social findings; the absence of findings, e.g. absent bowel sounds, the absence of a knee reflex, are not included within this Technical Specification as it might prejudice subsequent attempts at standardising the modelling of such instances; an exhaustive list of all possible characterising concepts that could be used to describe clinical findings.**		
ISO/TS 27527	Health informatics -- Provider identification	WP2, WP3, WP5, WP6, WP7
Description: This Technical Specification provides a framework for improving the positive identification of providers. Identification of "providers" encompasses individuals and organisations. This Technical Specification includes data elements needed for identification of individual providers (i.e. individuals) and data elements needed for the identification of organisation providers (i.e. organisations). "Identification" in this Technical Specification refers both to the process of being able to identify individuals and organisations, and the data elements required to support that identification manually and from a computer processing perspective. This Technical Specification can be applied to all providers of services, individuals and organisations. It details both data and processes for collection and application of identifying information for providers. It defines demographic and other identifying data elements suited to capture and use for the identification of providers in health care settings and provides guidance on their application. This Technical Specification provides: definitions of data elements to support the identification of individual providers and organisational providers for purposes such as electronic health record authentication and authorisation, communications, role definitions, delegation of authority, and the management of certification of individuals where more than one discipline is concerned; guidance on the development, population, governance and ongoing management of provider identifiers from multiple potential sources. This includes identification of processes to support national, multinational and provincial/state or local level identification. Unique identifier structures may differ for different purposes, or with different originating organisations. For this reason, a generic approach to the structure of these identifiers is given in this Technical Specification to support multiple unique identifiers and the ability to link these to the relevant provider. Annex A provides information to support the process of identification and implementation of provider identification in health care information systems. This Technical Specification is primarily concerned with provider identification data for clinical and administrative purposes. This Technical Specification is intended for use by health and health-related establishments that create, use or maintain records on providers. Establishments are intended to use this		

Technical Specification, where appropriate, for collecting data when registering providers. This Technical Specification does not include the process for development of unique identifiers. Standards for the development of identifiers are provided in ISO/TS 22220. Data required to meet identification purposes is highly dependent upon the place and purpose of identification. This Technical Specification identifies a range of data that support the identification of an individual or organisation used in different health care environments. EXAMPLE Some systems use a phone number to confirm that a call is coming from a bona fide location, specifically when confirming or requesting a fax. The phone number in this case is used as an additional item of identification. This Technical Specification does not attempt to identify all the use cases for which the items included are relevant; however, the data elements are provided to allow their consistent representation where they are found appropriate to support identification activities of the organisation or jurisdiction.		
ISO/TS 13606-4:2019	Health informatics -- Electronic health record communication -- Part 4: Security	WP2, WP3, WP5, WP6, WP7
Description: This document describes a methodology for specifying the privileges necessary to access EHR data. This methodology forms part of the overall EHR communications architecture defined in ISO 13606-1. This document seeks to address those requirements uniquely pertaining to EHR communications and to represent and communicate EHR-specific information that will inform an access decision. It also refers to general security requirements that apply to EHR communications and points at technical solutions and standards that specify details on services meeting these security needs. **NOTE: Security requirements for EHR systems not related to the communication of EHRs are outside the scope of this document.**		
ISO TR 12300:2014	Health informatics — Principles of mapping between terminological systems	WP2, WP3, WP5, WP6, WP7
Description: This Technical Report provides guidance for organisations charged with creating or applying maps to meet their business needs. It explains the risks inherent in the mapping process and discusses the issues that need to be considered in the development, maintenance, and use of maps in health care. This Technical Report also identifies variations in process, precision, and administration when mapping for different purposes and in different environments. Importantly, this Technical Report establishes and harmonises the basic principles for developing, maintaining, and using maps and gives guidelines for good practice that underpin the mapping process. Terminological resources include terminologies, classifications, and code systems used in the regulatory environment as it relates to healthcare and reporting requirements in healthcare. This Technical Report is general in nature and does not describe the specific methods applied in the mapping process nor does it describe maps between databases and data sets, even though many of the principles stated here will apply to those types of maps. This Technical Report does not include consideration of the intellectual property rights and expectations of the owners of terminologies or classifications. It is the responsibility of the mapper and process to		

ensure that these legal rights are protected and acknowledged as part of the mapping processes.		
EN 14484:2003	Health informatics - International transfer of personal health data covered by the EU data protection directive - High level security policy	WP4, WP6
Description: This item will provide guidance on the data protection policy which should be implemented by organisations which are participants in international applications which involve transfer of person identifiable data across national borders and which require compliance with the EU Data Protection Directive.		
EN 14485:2003	Health informatics - Guidance for handling personal health data in international applications in the context of the EU data protection directive	WP4, WP6
Description: This European Standard provides guidance on data protection for those involved in international informatics applications which entail transmission of person health data from an EU Member State to a non-EU Member State. Its purpose is to assist in the application of the EU Directive on Data Protection.		
IEC 80001-1:2010	Application of risk management for IT networks incorporating medical devices - Part 1: Roles, responsibilities and activities	WP2, WP3, WP5, WP6, WP7
Description: Recognising that medical devices are incorporated into IT networks to achieve desirable benefits (for example, interoperability), defines the roles, responsibilities and activities that are necessary for risk management of IT networks incorporating medical devices to address safety, effectiveness and data and system security (the key properties). IEC 80001-1:2010 does not specify acceptable risk levels. IEC 80001-1:2010 applies after a medical device has been acquired by a responsible organisation and is a candidate for incorporation into an IT network. It applies throughout the life cycle of IT networks incorporating medical devices. IEC 80001-1:2010 applies where there is no single medical device manufacturer assuming responsibility for addressing the key properties of the IT network incorporating a medical device. IEC 80001-1:2010 applies to responsible organisations, medical device manufacturers and providers of other information technology for the purpose of risk management of an IT network incorporating medical devices as specified by the responsible organisation. It does not apply to personal use applications where the patient, operator and responsible organisation are one and the same person.		
IEC TR 80001-1:2015	Application of risk management for IT	WP2, WP3, WP5, WP6, WP7

	networks incorporating medical devices	

Description: IEC/TR 80001-2-1:2012(E), which is a technical report, is a step-by-step guide to help in the application of risk management when creating or changing a medical IT network. It provides easy to apply steps, examples, and information helping in the identification and control of risks. All relevant requirements in IEC 80001-1:2010 are addressed and links to other clauses and subclauses of IEC 80001-1 are addressed where appropriate (e.g. handover to release management and monitoring). This technical report focuses on practical risk management. It is not intended to provide a full outline or explanation of all requirements that are satisfactorily covered by IEC 80001-1. This step-by-step guidance follows a 10-step process that follows subclause 4.4 of IEC 80001-1:2010, which specifically addresses risk analysis, risk evaluation and risk control. These activities are embedded within the full life cycle risk management process. They can never be the first step, as risk management follows the general process model which sets planning before any action. IEC/TR 80001-2-2:2012(E), which is a technical report, creates a framework for the disclosure of security-related capabilities and risks necessary for managing the risk in connecting medical devices to IT networks and for the security dialog that surrounds the IEC 80001-1 risk management of IT network connection. This security report presents an informative set of common, high-level security-related capabilities useful in understanding the user needs, the type of security controls to be considered and the risks that lead to the controls. Intended use and local factors determine which exact capabilities will be useful in the dialog about risk. The capability descriptions in this report are intended to supply health delivery organisations (HDOs), medical device manufacturers (MDMs), and IT vendors with a basis for discussing risk and their respective roles and responsibilities toward its management. This discussion among the risk partners serves as the basis for one or more responsibility agreements as specified in IEC 80001-1. IEC/TR 80001-2-3:2012(E), which is a technical report, supports the Healthcare Delivery Organisations (HDO) in the risk management of medical IT networks that incorporate one or more wireless links. The report, as part of IEC 80001, considers the use of wirelessly networked medical devices on a medical IT network and offers practical techniques to address the unique risk management requirements of operating wirelessly enabled medical devices in a safe, secure and effective manner. The targeted audience for this technical report is the HDO IT department, biomedical and clinical engineering departments, risk managers, and the people responsible for design and operation of the wireless IT network. IEC/TR 80001-2-4:2012(E), which is a technical report, provides guidance to help a healthcare delivery organisation fulfilling its obligations as a responsible organisation in the application of IEC 80001-1. A healthcare delivery organisation includes hospitals, doctors' offices, community care homes and clinics. Specifically, this guide helps the healthcare delivery organisation assess the impact of IEC 80001-1 on the organisation and establish a series of business-as-usual processes to manage RISK in the creation, maintenance and upkeep of its medical IT networks. This technical report will be useful to those responsible for establishing an IEC 80001-1 compliant risk management framework within a healthcare delivery organisation that is expecting to establish one or more medical IT networks. It provides help through the key decisions and steps required to establish a risk management framework, before the organisation embarks on a detailed risk assessment of an individual instance of a medical IT network. The steps are supported by a series of decision points to steer the responsible organisation through the process of understanding the medical IT network context and

identifying any organisational changes required to execute the responsibilities of top management. IEC TR 80001-2-5:2014(E) which is a technical report, gives guidance and practical techniques for responsible organisations, medical device manufacturers and providers of other information technology in the application of IEC 80001-1:2010 for the risk management of distributed alarm systems. This technical report applies to the transmission of alarm conditions between sources, integrator and communicators where at least one source is a medical device and at least one communication path utilises a medical IT network. This technical report provides recommendations for the integration, communication of responses and redirection (to another operator) of alarm conditions from one or more sources to ensure safety and effectiveness. Data and systems security is an important consideration for the risk management of distributed alarm systems. ISO/TR 80001-2-6:2014 provides guidance on implementing RESPONSIBILITY AGREEMENTS, which are described in IEC 80001-1 as used to establish the roles and responsibilities among the stakeholders engaged in the incorporation of a MEDICAL DEVICE into an IT NETWORK to support compliance to IEC 80001-1. Stakeholders may include RESPONSIBLE ORGANISATIONS, IT suppliers, MEDICAL DEVICE manufacturers and others. The goal of the RESPONSIBILITY AGREEMENT is that these roles and responsibilities should cover the complete lifecycle of the resulting MEDICAL IT NETWORK. ISO/TR 80001-2-7:2015 is to provide guidance to HDOs on self-assessment of their conformance against IEC 80001-1.

3.1.5 E-Health

Number	Title	Relevant for WP
HL7 FHIR R4	HL7 FHIR R4	WP2, WP3, WP5, WP6, WP7
Description: FHIR® – Fast Healthcare Interoperability Resources (hl7.org/fhir) – is a next generation standards framework created by HL7. FHIR combines the best features of HL7's v2 , HL7 v3 and CDA product lines while leveraging the latest web standards and applying a tight focus on implementability. **FHIR solutions are built from a set of modular components called "Resources". These resources can easily be assembled into working systems that solve real world clinical and administrative problems at a fraction of the price of existing alternatives. FHIR is suitable for use in a wide variety of contexts – mobile phone apps, cloud communications, EHR-based data sharing, server communication in large institutional healthcare providers, and much more.**		
HL7 CDS Hook	HL7 Cross-Paradigm Specification: CDS Hooks, Release 1	WP2, WP3, WP5, WP6, WP7
The CDS Hooks specification describes the RESTful APIs and interactions to integrate Clinical Decision Support (CDS) between CDS Clients (typically Electronic Health Record Systems (EHRs) or other health information systems) and CDS Services. All data exchanged through the RESTful APIs MUST be sent and received as JSON structures and MUST be transmitted over channels secured using the		

Hypertext Transfer Protocol (HTTP) over Transport Layer Security (TLS), also known as HTTPS and defined in RFC2818.		
EN 17269: 2019	Health informatics - The International Patient Summary	WP2, WP3, WP5, WP6, WP7
Description: This standard formalises the dataset required to share information about the medical background and history of a patient from the patient's country of affiliation with a healthcare professional in another country where unscheduled treatment is required. It uses the European guidelines (version 2, November 2016) as an official source for the requirements. The scope for the 'Patient Summary for Unscheduled, Cross-border Care' standard is of international significance. This standard, therefore, complements co-ordinated international efforts to maximise its utility and value, providing an interoperable dataset specification. The dataset is minimal and non-exhaustive, providing a robust, well-defined set of items that are specialty-agnostic, condition-independent and usable by all clinicians for the unscheduled care of a person. The dataset will also be usable as a valuable subset of data items for scheduled care. The dataset enables cross-border application and it will support national communication of patient summary data, thereby providing wider applicability and greater benefit from the standard for the continuity of care of a person in need. This international standard does not cover workflow processes of data entry, data collection, the summarisation act nor subsequent data presentation. Implementation guidance for specifically European concerns, e.g., Directives, terminologies, formats etc., is in the associated Technical Specification.		
ISO/DIS 27269	Health informatics - The International Patient Summary	WP2, WP3, WP5, WP6, WP7
Description: see EN 17269: 2019 description		
HL7 IPS FHIR IG	HL7 International Patient Summary FHIR Implementation Guide.EHR	WP2, WP3, WP5, WP6, WP7
Description: An International Patient Summary (IPS) document is an electronic health record extract containing essential healthcare information about a subject of care. The IPS dataset is minimal and non-exhaustive; specialty-agnostic and condition-independent; but still clinically relevant. As specified in EN 17269 and ISO/DIS 27269, it is designed for supporting the use case scenario for 'unplanned, cross border care', but it is not limited to it. It is intended to be international, i.e., to provide generic solutions for global application beyond a specific region or country.		
HL7 FHIR Vital Signs	HL7 FHIR Vital Signs Profile Sets	WP2, WP3, WP5, WP6, WP7
Description: Vital signs will be one of the first areas where there is a need for a single, global vocabulary to allow for ubiquitous access and re-use. Especially with the use of wearables by patients where they want/need to share information from those devices. To meet this need there must be a consistent vocabulary and a common syntax to achieve semantic interoperability. The FHIR Vital Signs profile sets		

minimum expectations for the Observation resource to record, search and fetch the vital signs associated with a patient that include the primary vital signs plus additional measurements such as height, weight and BMI		
EUR 27072	Mapping of effective technology-based services for independent living for older people at home. Deliverable 1	WP2, WP3, WP5, WP6, WP7
Description: This report identifies and maps technology-based services which have successfully enhanced the independent living of older adults at home in and outside Europe. This is the first deliverable of the research project "Long-term care strategies for independent living of older people (ICT-AGE)", as a study targeted to produce policy recommendations for DG EMPL to support Member States in their long-term care strategy, according to the EC policy priorities of the Social Investment Package, the European Semester and the European Innovation Partnership on Active and Healthy Ageing. We found 14 different, mature and mainstreamed technology-based services for the independent living of older adults at home that effectively address a set of long-term care needs. To the best of our knowledge, this is the first study that has managed to find scientific evidence to show for several practices in technology-based services which shows that they increase the independence of older people living at home, improve the productivity of carers, enable better quality of care, and generate savings, contributing to the financial sustainability of the long-term care systems.		
IHE MHD	Mobile Access to Health Documents	WP2, WP3, WP5, WP6, WP7
Description: IHE MHD defines transactions to -submit a new document and metadata from the mobile device to a document receiver, -get the metadata for an identified document, -find document entries containing metadata based on query parameters, and -retrieve a copy of a specific document. These transactions leverage the document content and format agnostic metadata concepts from XDS, but simplify them for access by constrained environments such as mobile devices. The MHD profile does not replace XDS. It can be used to allow mobile devices constrained access to an XDS health information exchange. The following figure shows one possible way to implement MHD with a document sharing environment (that may, but is not necessarily, XDS based).		
HL7 cMHAFF, Release 1	HL7 Consumer Mobile Health Application Functional Framework (cMHAFF), Release 1	WP2, WP3, WP5, WP6, WP7
The primary goals of cMHAFF are to provide a standard against which a mobile app's foundational characteristics -- including but not limited to security, privacy, data access, data export, and transparency/disclosure of conditions -- can be assessed. The framework is based on the lifecycle of an app, as experienced by an individual consumer, from first deciding to download an app, to determining what happens with consumer data after the app has been deleted from a smartphone. It is important to note that the Framework does not speak directly to the specific health		

or clinical functionality of an app but can be extended to do so using profiles (with constraints and/or extensions) developed on top of cMHAFF.		
IHE PCD	Patient Care Device	WP2, WP3, WP5, WP6, WP7
Description: IHE PCD addresses the integration of medical devices into the healthcare enterprise, from the point-of-care to the EHR, potentially resulting in significant improvements in patient safety and quality of care IHE Patient Care Device integration profiles include: [ACM] Alarm Communication Management enables the remote communication of point-of-care medical device alarm conditions ensuring the right alarm with the right priority to the right individuals with the right content (e.g., evidentiary data). It also supports alarm escalation or confirmation based on dissemination status, such as whether the intended clinician has received and acknowledged the condition. [DEC] Device Enterprise Communication supports publication of information acquired from point-of-care medical devices to applications such as clinical information systems and electronic health record systems, using a consistent messaging format and device semantic content. [DEC-PIB] Patient Identity Binding provides an optional extension to the DEC profile that supports a means of binding authenticated patient identity information to device data communication transactions. [DEC-SPD] Subscribe to Patient Data provides an optional extension to the DEC profile that supports a filtering mechanism using a publish / subscribe mechanism for applications to negotiate what device data they receive based on a set of client-specified predicates. [PIV] Point-of-care Infusion Verification supports communication of a 5-Rights validated medication delivery / infusion order from a BCMA system to an infusion pump or pump management system, thus "closing the loop." Optionally, the [DEC] profile may be used to selectively monitor the status of the devices that have been programmed. [RTM] Rosetta Terminology Mapping establishes a set of tools (Excel spreadsheets & XML files) that map the proprietary semantics communicated by medical devices today to a standard representation using ISO/IEEE 11073 semantics and UCUM units of measurement. Additionally, the Rosetta tables capture parameter co-constraints, specifying the set of units of measurement, body sites, and enumerated values that may be associated with a given parameter, thus enabling even more rigorous validation of exchanged medical device semantic content.		
SNOMED CT®	Snomed International: SNOMED CT®	WP2, WP3, WP5, WP6, WP7
Description: SNOMED CT allows a consistent way to index, store, retrieve, and aggregate clinical data across specialities and sites of care. It also helps in organising the content of medical records, reducing the variability in the way data is captured, encoded and used for clinical care of patients and research. The primary purpose of SNOMED CT is to support the effective clinical recording of data with the aim of improving patient care. It is a structured collection of medical terms that are used internationally for recording clinical information and are coded to be computer processable. It covers areas such as diseases, symptoms, operations, treatments, devices and drugs. Its purpose is to consistently index, store, retrieve, and aggregate clinical data across specialties and sites of care. It helps organising the content of electronic health records systems, reducing the variability in the way data is captured, encoded and used for clinical care of patients and research. Specific		

language editions are available which augment the international Edition and can contain language translations as well as additional national terms. SNOMED CT is considered by some to be the most comprehensive, multilingual clinical healthcare terminology in the world. It provides for consistent information interchange and is fundamental to an interoperable electronic health record. It can be used to record the clinical details of individuals in electronic patient records and support application functionality such as informed decision making, linkage to clinical care pathways and knowledge resources, shared care plans and as such support long term patient care. The availability of free automatic coding tools and services, which can return a ranked list of SNOMED CT descriptors to encode any clinical report, could help healthcare professionals to navigate the terminology. **NOTE: SNOMED International does not charge for use of SNOMED CT in SNOMED International Member countries or territories. Charges may apply for affiliate use of SNOMED CT in non-Member territories and are calculated based on use as well as the territory as determined by the World Bank.**		
SNOMED CT® GPS	Snomed International: SNOMED CT® Global Patient Set	WP2, WP3, WP5, WP6, WP7
Description: The Global Patient Set (GPS) is a managed collection of existing SNOMED CT reference sets released by SNOMED International. The GPS is comprised of unique identifiers, fully specified names (FSN), preferred terms in international English, and active/inactive status flags. **The GPS excludes SNOMED CT's inherent relationships and hierarchies; fundamental to the nature of an ontology and its ability to enable clinical data analytics, decision support, artificial intelligence, etc. Further, concept synonyms and definitions are not provided as part of the GPS.** **NOTE: The Global Patient Set is produced by SNOMED International and is licensed under the Creative Commons Attribution 4.0 International License. The GPS is made available to users at no cost.**		
WHO ATC	WHO Anatomical Therapeutic Chemical (ATC) classification system	WP2, WP3, WP5, WP6, WP7
Description: The Anatomical Therapeutic Chemical (ATC) Classification System is a drug classification system that classifies the active ingredients of drugs according to the organ or system on which they act and their therapeutic, pharmacological and chemical properties.		
EDQM ST	EDQM Standard Terms	WP2, WP3, WP5, WP6, WP7
Description: The Standard Terms database contains terms and definitions to describe pharmaceutical dose forms, routes and methods of administration, containers, closures, administration devices and units of presentation. It contains agreed combinations of terms, for example to describe where two or more items are packaged together, or where a pharmaceutical dose form and a container are described using a single term. It also contains patient-friendly terms, which are		

generally shorter terms that, where justified and authorised by the competent authority, may be used on certain labels where space is limited.		
UCUM®	Regenstrief Institute, Inc. : The Unified Code for Units of Measure	WP2, WP3, WP5, WP6, WP7
Description: The Unified Code for Units of Measure (UCUM) is a code system intended to include all units of measures being contemporarily used in international science, engineering, and business. The purpose is to facilitate unambiguous electronic communication of quantities together with their units. The focus is on electronic communication, as opposed to communication between humans.		
LOINC®	Regenstrief Institute, Inc. : LOINC (Logical Observation Identifiers Names and Codes)	WP2, WP3, WP5, WP6, WP7
Description: LOINC is a common language (set of identifiers, names, and codes) for identifying health measurements, observations, and documents. If you think of an observation as a "question" and the observation result value as an "answer."		
UMLS	Unified Medical Language System	WP2, WP3, WP5, WP6, WP7
Description: UMLS consists of three parts: Metathesaurus, Semantic Network and SPECIALIST Lexicon. **Metathesaurus: The Metathesaurus forms the base of the UMLS and comprises over 1 million biomedical concepts and 5 million concept names, all of which stem from the over 100 incorporated controlled vocabularies and classification systems. Some examples of the incorporated controlled vocabularies are ICD-10, MeSH, SNOMED CT, DSM-IV, LOINC, WHO Adverse Drug Reaction Terminology, UK Clinical Terms, RxNorm, Gene Ontology, and OMIM. The Metathesaurus is organised by concept, and each concept has specific attributes defining its meaning and is linked to the corresponding concept names in the various source vocabularies.** **Semantic Network: Each concept in the Metathesaurus is assigned one or more semantic types (categories), which are linked with one another through semantic relationships. The semantic network is a catalogue of these semantic types and relationships. This is a rather broad classification; there are 135 semantic types and 54 relationships in total.** **SPECIALIST Lexicon: The SPECIALIST Lexicon contains information about common English vocabulary, biomedical terms, terms found in MEDLINE and terms found in the UMLS Metathesaurus. Each entry contains syntactic (how words are put together to create meaning), morphological (form and structure) and orthographic (spelling) information. A set of Java programmes use the lexicon to work through the variations in biomedical texts by relating words by their parts of speech, which can be helpful in web searches or searches through an electronic medical record.**		
BlueRobin	BlueRobin	WP2, WP3, WP5, WP6, WP7

Description: The target of the BlueRobinTM protocol is to provide low data rates for wireless body area sensor networks and team monitoring systems at ultra-low power consumption combined with high reliability and low hardware costs. The effective data rate is selectable from 8 bits up to 256 bits per data packet with an interval between packet transmissions in the range of 500 ms up to 1 second. Current Consumption: The transmitter and receiver current consumption is small enough to enable the realisation of body area systems consisting of a receiver and up to 3 transmitters that can be operated with standard CR2032 batteries for more than 2 years. Following conditions apply: Transmission distance at least 3 meters System usage rate is one hour / day Reliability To reduce hardware costs and current consumption as much as possible the protocol is based on a unidirectional transmission, however for applications sensitive to data loss a bidirectional acknowledgement system including a smart packet collision avoidance method is available. To enhance data reliability in case of a unidirectional system redundant transmission including a patented packet collision minimisation method is provided. If a sensor needs to be controlled and configured from the receiver side an optional messaging system allows sending data to the sensor. This feature causes a slightly increased current consumption on the sensor side. It also allows to switch sensors on and off from the receiver side in a very power efficient way. When using this messaging system, transceiver chips must be used on both sides. Unique Serial Numbers and Type Specifiers To allow unique identification of transmitters, a type specifier and a serial number (also called transmitter ID) is assigned to every module. The type specifier is used to determine the kind of data a module delivers and therefore the way it has to be interpreted (i.e. speed data, heart rate data …). The serial number is unique for every transmitter. Both type specifier and serial number are contained in every data packet that is transmitted.		
WHO ICD	The International Classification of Diseases	WP2, WP3, WP5, WP6, WP7
Description: ICD is the foundation for the identification of health trends and statistics globally, and the international standard for reporting diseases and health conditions. It is the diagnostic classification standard for all clinical and research purposes. ICD defines the universe of diseases, disorders, injuries and other related health conditions, listed in a comprehensive, hierarchical fashion that allows for: • **easy storage, retrieval and analysis of health information for evidenced-based decision-making;** • **sharing and comparing health information between hospitals, regions, settings and countries; and** • **data comparisons in the same location across different time periods.** **Uses include monitoring of the incidence and prevalence of diseases, observing reimbursements and resource allocation trends, and keeping track of safety and quality guidelines. They also include the counting of deaths as well as diseases, injuries, symptoms, reasons for encounter, factors that influence health status, and external causes of disease.** **ICD has several versions and localisations. Most relevant are: ICD-9; ICD-9-CM; ICD-10; ICD-10-CM; ICD-10-PCS; ICD-11.**		

WHO ICF	International Classification of Functioning, Disability and Health (ICF)	WP2, WP3, WP5, WP6, WP7
Description: The International Classification of Functioning, Disability and Health, known more commonly as ICF, is a classification of health and health-related domains. As the functioning and disability of an individual occurs in a context, ICF also includes a list of environmental factors.		
VDE-AR-M 3756-1	Quality management for telemonitoring in medical applications	WP2, WP3, WP5, WP6, WP7
Description: This document specifies requirements for a quality management system for telemonitoring for an organisation.		

3.1.6 Health care

Number	Title	Relevant for WP
EN 13940-1:2015	Health informatics - System of concepts to support continuity of care - Part 1: Basic concepts	WP2, WP3, WP7

Description:

Main purpose: Continuity of care implies the management of health information in two different perspectives: local management of information about the subject of care, at the site of care provision; information interchange between health care providers.

NOTE: Record management: Continuity of care requires that every contact and every health care provider activity, in or out of the presence of the subject of care, be recorded. Those health care activities that are performed by health care third parties should also be recorded to support continuity. If ever a contact or a health care activity is not recorded, while it remains a contact or health care activity, its contribution to seamless or integrated care can be ignored, and continuity of care jeopardised.

This European Standard seeks to identify and define those processes which relate to the continuity of health care provided to human beings (to the exclusion of other living subjects). It specifically addresses aspects of sharing subject of care related information needed in the process of health care. It identifies and defines relevant data and information flows, together with their relationships to "time slots". In order to support the delivery of high-quality care to each subject of care, and to facilitate continuity of care, a full understanding is needed of the temporal aspects of the delivery of health care, the role of each party in the health care process, and their interaction in the subjects of care environment. The concepts describing the characteristics of the ongoing process of care should not differ in nature from those that are used to structure and organise the data locally in the Electronic Health Record.

This European Standard addresses such topics as: a) organisational principles of health care; b) health care actors, health care parties, subjects of care, health care providers, provider organisations, health care professionals and third parties; c) health issues and their managing.		
EN 15224:2016	Health care services - Quality management systems - Requirements based on EN ISO 9001:2008	WP2, WP3, WP7
Description: This European standard specifies requirements for a quality management system where an organisation: a) needs to demonstrate its ability to consistently provide health care services that meet requirements from customers as well as applicable statutory and regulatory requirements, and professional standards b) aims to enhance customer satisfaction through the effective application of the system, including continual improvement of the management system, the clinical processes and the assurance of conformity to requirements related to the quality characteristics ; appropriate, correct care; availability; continuity of care; effectiveness; efficiency; equity; evidence/knowledge based care; patient centred care including physical and psychological integrity; patient involvement; patient safety and timelines/accessibility. Material products such as tissue, blood products, pharmaceuticals, cell culture products and medical devices have not been focused on the scope of the standard as they are regulated elsewhere. This European Standard is focused on requirements for clinical processes. Organisations that also include research or education processes, or both in their quality management system could use the requirements in this European Standard where applicable. This European Standard aims to adjust and specify the requirements, as well as the "product" concept and customer perspectives in EN ISO 9001:2008 to the specific conditions for health care where products are mainly services and customers are mainly patients. The focus of this European Standard is the clinical processes and their risk management to promote good quality health care. 1.2 Application This European Standard a) gives requirements for systematic approaches for the organisation's ability to produce good quality health care. b) can be used by management at all levels in the health care organisation to implement and maintain a quality management system or by internal and external parties, including certification bodies, to assess the organisation's ability to meet patients' needs and expectations as well those from other customers. c) is applicable to health care organisations, regardless of structure, organisation, owner, size or type of health care services provided. d) is applicable to e.g. primary health care, pre-hospital and hospital care, tertiary care, nursing homes, hospices, preventive health care, mental health services, dental services, physiotherapy, occupational health services and pharmacies. e) is focused on requirements for clinical processes. Organisations that also include research or education processes, in the scope of their quality management system could use the requirements in this standard where applicable. Where any requirement(s) of this European Standard cannot be applied due to the nature of a health care organisation and its product (including services), this can be considered for exclusion. Where exclusions are made, claims of conformity to this European Standard are not acceptable unless these exclusions are limited to requirements within Clause 7, and such exclusions do not affect the health care organisation's ability, or responsibility, to provide products (including		

services) that meets customer and applicable statutory and regulatory requirements.		
EN ISO 9000:2015	Quality management systems - Fundamentals and vocabulary (ISO 9000:2015)	WP2, WP7
Description: ISO 9000:2015 describes the fundamental concepts and principles of quality management which are universally applicable to the following: · organisations seeking sustained success through the implementation of a quality management system; · customers seeking confidence in an organisation's ability to consistently provide products and services conforming to their requirements; · organisations seeking confidence in their supply chain that their product and service requirements will be met; · organisations and interested parties seeking to improve communication through a common understanding of the vocabulary used in quality management; · organisations performing conformity assessments against the requirements of ISO 9001; · providers of training, assessment or advice in quality management; · developers of related standards. ISO 9000:2015 specifies the terms and definitions that apply to all quality management and quality management system standards developed by ISO/TC 176.		
ISO 10004:2018	Quality management - Customer satisfaction - Guidelines for monitoring and measuring	WP2, WP7
Description: This document gives guidelines for defining and implementing processes to monitor and measure customer satisfaction. This document is intended for use by any organisation regardless of its type or size, or the products and services it provides. The focus of this document is on customers external to the organisation. **NOTE: Throughout this document, the terms "product" and "service" refer to the outputs of an organisation that are intended for, or required by, a customer.**		
ETSI TR 102 415:2005	Human Factors (HF);Telecare services; Issues and recommendations for user aspects	WP2, WP7
Description: The present document addresses the end user aspects of telecare, with emphasis on the delivery of health and social care services, in and outside of connected (intelligent) homes, with the purpose of ensuring that human factors aspects are duly considered in the current rapid progress towards ICT-based delivery of health care services. The present document identifies key stakeholders including end users (comprising clients, the person in need of care and health professionals, informal carers and care coordinators), their objectives and requirements, with the following perspectives: • **the enhancement of human interaction by ICT;** • **proliferation of personal data and privacy concerns; and** • **safety and security of equipment use, misuse, non-use and malfunctioning.**		

Furthermore, the present document identifies and examines technical, organisational and cost-related barriers to the widespread deployment, adoption and use of telecare services, and recommends strategies to overcome these barriers. The present document considers requirements of the widest possible generic client population, including the needs of older people, babies, children and disabled clients. The present document provides generic guidance and specific recommendations to standards developers, operators, service providers, equipment suppliers, policy makers, designers and users of telecare services, applicable to: • **telecare service provision elements;** • **stakeholders' concerns; and** • **ethical, privacy and security aspects. The present document should be considered as a human factors and user experience standardisation study, "setting the scene". In addition, the present document provides recommendations for future work, including the development of human factors guidelines, recommended to be initiated as soon as possible.**		
SS 872500:2015	Quality of care, service, nursing and rehabilitation for elderly people with extensive needs in ordinary and residential care facilities (Swedish standard) https://www.sis.se/produkter/foretagsorganisation/tjanster/tjanster/ss872500 2015/	WP2, WP7
Description: This guide describes and explains various aspects of The SS 872500:2015 Quality of care, service, care and rehabilitation for the elderly with extensive needs in ordinary and special housing. **The guidance starts with an orientation chapter on standardisation.** **The work on the Elderly Standard and an international outlook are then outlined.** **The structure of the standard is then described and the view of the older, person-centred approach, which is the main element of the standard.** **Furthermore, the concept of the process is described in relation to activities and routines and self-control.** **The guidance also describes how the area of knowledge and competence can be handled according to the standard.**		

3.2 Home

The following are relevant standards for home appliances, including domestic robotics, alarms, welfare technology and others.

3.2.1 Sensors, actuators and alarms

Number	Title	Relevant for WP

EN 50130-4:2014	Alarm systems - Part 4: Electromagnetic compatibility - Product family standard: Immunity requirements for components of fire, intruder, hold up, CCTV, access control and social alarm systems	WP3, WP4, WP5
Description: This EMC product-family standard, for immunity requirements, applies to the components of the following alarm systems, intended for use in and around buildings in residential, commercial, light industrial and industrial environments:– access control systems, for security applications;– alarm transmission systems 1);– CCTV systems, for security applications;– fire detection and fire alarm systems;– hold-up alarm systems;– intruder alarm systems;– social alarm systems; The tests and severities to be used are the same for indoor and outdoor applications of fixed, movable and portable equipment. The levels do not cover extreme cases, which may occur in any location, but with an extremely low probability of occurrence, or in special locations close to powerful emitters (e.g. radar transmitters). Equipment within the scope of this standard should be designed to operate satisfactorily in the environmental electromagnetic conditions of residential, commercial, and other circumstances.		
EN 50364:2018	Limitation of human exposure to electromagnetic fields from devices operating in the frequency range 0 Hz to 300 GHz, used in Electronic Article Surveillance (EAS), Radio Frequency Identification (RFID) and similar applications	WP3, WP4, WP5
Description: This product standard applies to devices operating within the frequency range 0 Hz to 300 GHz, used in electronic article surveillance (EAS), radio frequency identification (RFID) and similar applications, in relation to exposure to electromagnetic fields The object of this generic standard is to provide a route for evaluation of such equipment against limits on human exposure to electric, magnetic and electromagnetic fields, and induced and contact current. **NOTE: Other standards can apply to products covered by this document. This document is not designed to evaluate the electromagnetic compatibility with other equipment; nor does it reflect any product safety requirements other than those specifically related to human exposure to electromagnetic fields.**		
EN 55014:2017	Electromagnetic compatibility - Requirements for household appliances,	WP3, WP4, WP5

	electric tools and similar apparatus	
Description: EN 55014-1 applies to the conduction and the radiation of radio-frequency disturbances from appliances whose main functions are performed by motors and switching or regulating devices, unless the R.F. energy is intentionally generated or intended for illumination. It includes such equipment as: household electrical appliances, electric tools, regulating controls using semiconductor devices, motor-driven electro-medical apparatus, electric/ electronic toys, automatic dispensing machines as well as cine or slide projectors. [source: IHS.com] EN 55014-2 specifies the immunity requirements in relation to continuous and transient, conducted and radiated electromagnetic disturbances, including electrostatic discharges, for the above-mentioned apparatus. Apparatus may incorporate motors, heating elements or their combination, may contain electric or electronic circuitry, and may be powered by the mains, by batteries, or by any other electrical power source. Immunity requirements in the frequency range 0 Hz to 400 GHz are covered. [Source: CENELEC]		

3.2.2 Smart house technology

Number	Title	Relevant for WP
CLC/TS 50560:2014	Interoperability framework requirement specification	WP3, WP4, WP5
Description: This Technical Specification contains a specification of an Interoperability Requirements Framework, specifying seven levels of interoperability, based on four groups of interoperability steps specified by five types of interaction, plus a methodology based on conformance clauses for satisfying requirements related to the claimed level of interoperability of devices installed in a Home and Building Electronic System (HBES, HES).It is applicable to installations of a single type of HBES, or that interconnect two or more dissimilar HBESs. Within a HBES of a single type any of its capabilities for service, applications and connectivity topology can be used. Interconnection technologies used to interconnect dissimilar HBES are similarly unconstrained. For applicable installations, the scope of its provisions applies to the connection of devices to the various communications services to enable them to communicate end-to-end across internetworked media.		
ISO/TR 37150:2014	Smart community infrastructures -- Review of existing activities relevant to metrics	WP3, WP4, WP5
Description: This Technical Report provides a review of existing activities relevant to metrics for smart community infrastructures. In this Technical Report, the concept of smartness is addressed in terms of performance relevant to technologically implementable solutions, in accordance with sustainable development and resilience of communities, as defined in ISO/TC 268. This Technical Report addresses community infrastructures such as energy, water, transportation, waste and information and communications technology (ICT). It focuses on the technical		

aspects of existing activities which have been published, implemented or discussed. Economic, political or societal aspects are not analysed in this Technical Report. **NOTE: This Technical Report is not a recommendation document for best practices. Although sustainability objectives have been considered, the main subject of this Technical Report is the analysis of existing methodologies for smart community infrastructures.**		
ISO/IEC 15067-3:2016	Information technology — Home Electronic System (HES) application model — Part 3	WP3, WP4, WP5
Description: ISO/IEC 15067-3:2012(E) specifies an energy management model for programmes that manage the consumer demand for electricity using a method known as "demand response". Three types of demand response are specified in this standard: direct control, local control and distributed control. It replaces ISO/IEC TR 15067-3, first edition, published in 2000, and constitutes a technical revision. It includes the following significant technical changes with respect to the previous edition: the demand response options have been expanded; distributed energy resources such as local generation and storage have been included; the terminology for demand response has been aligned with smart grid.		
IEC/TR 62939-1:2014	Smart grid user interface – Part 1: Interface overview and country perspectives	WP3, WP4, WP5
Description: IEC TR 62939-1:2014(E) presents an international consensus perspective on the vision for a Smart Grid User Interface (SGUI) including: SGUI requirements distilled from use cases for communications across the customer interface (the SGUI); an analysis of existing IEC and other international standards that relate to the SGUI; and an identification of standards gaps that need to be filled and might become potential work items in IEC. The committee's scope is, "Standardisation in the field of information exchange for demand response and in connecting demand side equipment and/or systems into the Smart Grid". This report presents the information exchange and interface requirements leading to standards to support effective integration of consumer systems and devices into the Smart Grid.		

3.2.3 Accessibility to housing, packaging and others

Number	Title	Relevant for WP
EN 862:2016	Packaging - Child-resistant packaging - Requirements and testing procedures for non-reclosable packages for non-pharmaceutical products	WP2, WP7
Description: This European Standard specifies performance requirements and methods of test for non-reclosable packaging that has been designated child-		

resistant and which is intended to contain non-pharmaceutical products. This European standard is intended for type approval only (2.5) and is not intended for quality assurance purposes. This European Standard applies to non-reclosable packages of the single-use type consisting of one or more individual units. Non-reclosable packages for pharmaceutical products are excluded from the scope of this European standard. These are the subject of a separate standard, EN 14375, Child-resistant non-reclosable packaging for pharmaceutical products - Requirements and testing.		
CEN/TS 15945:2002	Packaging - Ease of opening - Criteria and test methods for evaluating consumer packaging	WP2, WP7
Description: This Technical Specification specifies the following for all adult consumers: - criteria for ease of opening of packages; - methods for evaluating the ease of opening of consumer packages. The purpose of this Technical Specification is to specify test methods to evaluate the ease of opening of consumer packages, to improve easy access to the contents. For packages regulated for safety or similar reasons, e.g. packaging of dangerous goods and substances, medicinal products, and medical devices, those regulations take precedence. This Technical Specification applies to all packaging that does not require an opening tool and to packaging that is purchased with an integrated opening tool. **NOTE 1: The method(s) described in this Technical Specification could also be applicable to other types of packages when measuring ease of opening.** **NOTE 2: This Technical Specification can be used to test most consumer packages. There are, however, certain packaging types that cannot easily be tested with the described methods, such as e.g. very large packaging used to protect refrigerators and washing machines.**		
EN ISO 11683:1997	Packaging - Tactile warnings of danger - Requirements (ISO 11683:1997)	WP2, WP7
Description: This standard specifies the requirements for a tactile warning of danger on packaging which contain certain dangerous substances and preparations. To prevent confusion in interpretation, the tactile warning of danger is affixed only on packages covered by the regulations in force on the dangerous substances and preparations. This standard does not specify the dangerous substances and preparations to be contained in packaging with a tactile warning of danger. These are to be specified by legislative authorities.		
ISO 11156:2011	Packaging -- Accessible design -- General requirements	WP2, WP7
Description: ISO 11156:2011 provides a framework for design and evaluation of packages so that more people, including persons from different cultural and linguistic backgrounds, older adults and persons whose sensory, physical, and cognitive functions have been weakened or have allergies, can appropriately identify handle and use the contents. It considers varying aspects of the packaged		

product lifecycle from identification of the product and purchase and use of the product to the separation and disposal of the package. ISO 11156:2011 does not apply to dimensions, materials, manufacturing methods, or evaluation methods of individual packages.		
CEN/CLC Guide 6:2014	Guide for addressing accessibility in standards	WP2, WP7
Description: Equivalent to ISO/IEC Guide 71:2014. This Guide provides guidance to standards developers on addressing accessibility requirements and recommendations in standards that focus, whether directly or indirectly, on systems (i.e. products, services and built environments) used by people. To assist standards developers to define accessibility requirements and recommendations, the Guide presents: - a summary of current terminology relating to accessibility; - issues to consider in support of accessibility in the standards development process; - a set of accessibility goals (used to identify user accessibility needs); - descriptions of (and design considerations for) human abilities and characteristics; - strategies for addressing user accessibility needs and design considerations in standards.		
CEN/TS 16118:2012	Sheltered housing - Requirements for services for older people provided in a sheltered housing scheme	WP2, WP7
Description: This CEN/TS applies to all providers of sheltered housing irrespective of the legal form of ownership and whether the service is publicly or privately funded. Its primary purpose is to improve and maintain standards of sheltered housing services and not that of the building design or specification. This CEN/TS primarily applies to new build sheltered housing schemes, but providers may choose to apply this to existing schemes where circumstances permit. This CEN/TS refers to facilities of sheltered housing for older people living in a sheltered housing scheme only and is not applicable to services required for nursing homes.		

3.3 Personal autonomy – assistive technology

3.3.1 Assistive technology

Assistive technology (AT) is assistive, adaptive, and rehabilitative devices for people with disabilities or the elderly population. Activities of daily living (ADLs) are self-care activities that include toileting, mobility (ambulation), eating, bathing, dressing, grooming, and personal device care, which for many elderly people can be a challenge. Assistive technology can ameliorate the effects of disabilities, age-related or otherwise, that limit the ability to perform ADLs. Assistive technology promotes greater independence by enabling people to perform tasks they were formerly unable to accomplish, or had great difficulty accomplishing, by providing enhancements to, or changing methods of interacting with, the technology needed to accomplish such tasks.

The standards in this field have an impact on, among other things, the development of technical aids and medical equipment relevant to welfare technology.

Number	Title	Relevant for WP
EN 12182:2012	Assistive products for persons with disability - General requirements and test methods	WP2, WP7
Description: This European Standard specifies general requirements and test methods for assistive products for persons with a disability, which are medical devices according to the definition laid down in the EU Directive 93/42/EEC. This European Standard does not apply to assistive products which achieve their intended purpose by administering pharmaceutical substances to the user. Where other European Standards exist for specific types of assistive products then those standards apply. However, some of the requirements of this standard may still apply and may be considered in addition to those in other European standards. **NOTE: Not all the items listed in EN ISO 9999 are medical devices. Contracting parties may wish to consider if this standard or parts of this standard can be used for assistive products which are not medical devices as defined in the EU Directive 93/42/EEC.**		
EN 60268-16:2011	Sound system equipment - Part 16: Objective rating of speech intelligibility by speech transmission index	WP2, WP7
Description: IEC 60268-16:2011 specifies objective methods for rating the transmission quality of speech with respect to intelligibility. It provides a comprehensive manual for all types of users of the STI method in the fields of audio, communications and acoustics. Three methods are presented, which are closely related and are referred to as STI, STIPA, and STITEL. The first two methods are intended for rating speech transmission performance with or without sound systems. The STITEL method has more restricted uses. This fourth edition cancels and replaces the third edition, published in 2003, and constitutes a technical revision. It includes the following significant technical changes with respect to the previous edition: - development of more comprehensive, complete and unambiguous standardisation of the STI methodology; - the term STI is discontinued. A new function for the prediction of auditory masking effects is introduced; - the concept of 'speech level' and the setting of the level of the test signal have been introduced; - additional information has been included on prediction and measurement procedures.		
EN 14375:2016	Child-resistant non-reclosable packaging for pharmaceutical products - Requirements and testing	WP2, WP7
Description: This European Standard specifies performance requirements and methods of test for non-reclosable packaging that have been designated child-resistant. This standard is intended for type approval only (see 3.5) and is not intended for quality assurance purposes.		

EN 61669:2016	Electroacoustics - Equipment for the measurement of real-ear acoustical characteristics of hearing aids	WP2, WP7
Description: Specifies the general requirements for test equipment designed for use in measuring the real-ear acoustical characteristics of hearing aids and describes the terminology used. The purpose of this International Standard is to ensure that measurements of real-ear acoustical characteristics of a hearing aid on a given human ear, performed with different test equipment which comply with this International Standard using methods described in ISO 12124, shall give substantially the same results.		
EN 60118:2015	Electroacoustics - Hearing aids	WP 2, WP 7
Description: CENELEC - IEC series of standards on hearing aids.		
EN 60318:2009	Electroacoustics - Simulators of human head and ear	WP2, WP7
Description: CENELEC - IEC series of standards on simulators of human head and ear		
EN 62489:2014	Electroacoustics - Audio-frequency induction loop systems for assisted hearing	WP2, WP7
Description: EN 62489 consists of 2 CENELEC-IEC Standards on audio-frequency induction loop systems for assisted hearing.		
EN ISO 9999:2016	Assistive products for persons with disability - Classification and terminology (ISO 9999:2016)	WP2, WP7
ISO 9999 establishes a classification of assistive products, especially produced or generally available, for persons with disability. Assistive products used by a person with disability, but which require the assistance of another person for their operation, are included in the classification. The following items are specifically excluded from ISO 9999: items used for the installation of assistive products; solutions obtained by combinations of assistive products that are individually classified in ISO 9999; medicines; assistive products and instruments used exclusively by healthcare professionals; non-technical solutions, such as personal assistance, guide dogs or lip-reading; implanted devices; and financial support.		
EN ISO 24503:2011	Ergonomics - Accessible design - Tactile dots and bars on consumer products (ISO 24503:2011)	WP2, WP7

Description: ISO 24503:2011 specifies requirements for the design of tactile dots and tactile bars for use on consumer products to improve accessibility for everyone, including older persons and persons with disabilities. ISO 24503:2011 is applicable to consumer products used by persons with visual disabilities, and in cases where visual information is not the primary sense used for accomplishing the task. Alternative tactile methods, such as texture and vibration, and other tactile symbols, such as triangles and squares, are not covered in ISO 24503:2011. Alternative feedback methods, such as in acoustic and visual modalities, are not covered in ISO 24503:2011.		
ISO 13482:2014	Robots and robotic devices -- Safety requirements for personal care robots	WP2, WP3, WP7
Description: ISO 13482:2014 specifies requirements and guidelines for the inherently safe design, protective measures, and information for use of personal care robots, in particular the following three types of personal care robots: • **mobile servant robot;** • **physical assistant robot;** • **person carrier robot.** **These robots typically perform tasks to improve the quality of life of intended users, irrespective of age or capability. ISO 13482:2014 describes hazards associated with the use of these robots, and provides requirements to eliminate, or reduce, the risks associated with these hazards to an acceptable level. ISO 13482:2014 covers human-robot physical contact applications. ISO 13482:2014 presents significant hazards and describes how to deal with them for each personal care robot type. ISO 13482:2014 covers robotic devices used in personal care applications, which are treated as personal care robots. ISO 13482:2014 is limited to earthbound robots. ISO 13482:2014 does not apply to:** • **robots travelling faster than 20 km/h** • **robot toys;** • **water-borne robots and flying robots;** • **industrial robots, which are covered in ISO 10218;** • **robots as medical devices;** • **military or public force application robots.** **The scope of ISO 13482:2014 is limited primarily to human care related hazards but, where appropriate, it includes domestic animals or property (defined as safety-related objects), when the personal care robot is properly installed and maintained and used for its intended purpose or under conditions which can reasonably be foreseen. ISO 13482:2014 is not applicable to robots manufactured prior to its publication date. ISO 13482:2014 deals with all significant hazards, hazardous situations or hazardous events as described in Annex A. Attention is drawn to the fact that for hazards related to impact (e.g. due to a collision) no exhaustive and internationally recognised data (e.g. pain or injury limits) exist at the time of publication of ISO 13482:2014.**		

ISO 16201:2006	Technical aids for persons with disability -- Environmental control systems for daily living	WP2, WP7
Description: ISO 16201:2006 specifies functional and technical requirements and test methods for environmental control systems intended for use to alleviate or compensate for a disability. Such systems are also known as electronic aids to daily living. The aim of ISO 16201:2006 is to provide safety requirements and recommendations for manufacturers of such environmental control systems. Target devices are not covered by ISO 16201:2006. Technical requirements for items of equipment connected within the system are to be covered by their own specific standards, e.g. adjustable beds.		
IEC 60118:2015	Electroacoustics - Hearing aids	WP2, WP7
Description: IEC 60118 consists of the following parts: - Part 0: Measurement of the performance characteristics of hearing aids - Part 4: Induction-loop systems for hearing aid purposes - System performance requirements - Part 5: Nipples for insert earphones - Part 7: Measurement of the performance characteristics of hearing aids for production, supply and delivery quality assurance purposes - Part 8: Methods of measurement of performance characteristics of hearing aids under simulated in situ working conditions - Part 9: Methods of measurement of characteristics of hearing aids with bone vibrator output - Part 12: Dimensions of electrical connector systems - Part 13: Electromagnetic compatibility (EMC) - Part 13: Electromagnetic compatibility (EMC) - Part 14: Specification of a digital interface device - Part 15: Methods for characterising signal processing in hearing aids with a speech-like signal		

3.4 Information and communication technology and data

3.4.1 Data and data collection

Number	Title	Relevant for WP
EN 62974-1:2017	Monitoring and measuring systems used for data collection, gathering and analysis - Part 1: Device requirements	WP4, WP6
CWA 15499-1:2006	Personal Data Protection Audit Framework (EU Directive EC 95/46) - Part I: Baseline Framework	WP4, WP6

Description: In this CWA a good practice audit framework for organisations to audit their processing of personal data is presented. Besides guidance on the audit process, two sets of requirements are presented in this framework:1. The first set of requirements 'compliance with the principles of the Directive' is about the personal data protection (PDP) system, that is the set of documented policies, codes of practice, guidelines and procedures the organisation has taken to achieve and retain compliance with personal data protection regulations, and whether personal data is in practice handled in accordance with this set.2. The second set of requirements 'governance' is about the internal controls around organisation, process and technology the organisation has implemented to ensure that personal data protection is addressed in a transparent, efficient and effective manner.		
EN ISO 19762-1:2012	Information technology - Automatic identification and data capture (AIDC) techniques - Harmonized vocabulary - Part 1: General terms relating to AIDC (ISO/IEC 19762-1:2008)	WP4, WP6
Description: ISO/IEC 19762-1:2008 provides general terms and definitions in the area of automatic identification and data capture techniques on which are based further specialised sections in various technical fields, as well as the essential terms to be used by non-specialist users in communication with specialists in automatic identification and data capture techniques.		
ISO 22514-3:2008	Statistical methods in process management — Capability and performance — Part 3: Machine performance studies for measured data on discrete parts	WP4, WP6
Description: This part of ISO 22514 prescribes the steps to be taken in conducting short-term performance studies that are typically performed on machines where parts produced consecutively under repeatability conditions are considered. The number of observations to be analysed will vary according to the patterns the data produce, or if the runs (the rate at which items are produced) on the machine are low in quantity. The methods are not recommended where the sample size produced is less than 30 observations. Methods to be used for handling the data and carrying out the calculations are described. In addition, machine performance indices and the actions required at the conclusion of a machine performance study are described. The document is not applicable when tool wear patterns are expected to be present during the duration of the study, nor if autocorrelation between observations is present. The situation where a machine has captured the data, sometimes thousands of data points collected in a minute, is not considered suitable for the application of this part of ISO 22514.		
ISO/TS 17975:2015	Health informatics — Principles and data	WP4, WP6

	requirements for consent in the Collection, Use or Disclosure of personal health information	

Description: This Technical Specification defines the set of frameworks of consent for the Collection, Use and/or Disclosure of personal information by health care practitioners or organisations that are frequently used to obtain agreement to process the personal health information of subjects of care. This is in order to provide an Informational Consent framework which can be specified and used by individual policy domains (e.g. healthcare organisations, regional health authorities, jurisdictions, countries) as an aid to the consistent management of information in the delivery of health care services and the communication of electronic health records across organisational and jurisdictional boundaries. The scope of application of this Technical Specification is limited to Personal Health Information (PHI) as defined in ISO 27799 information about an identifiable person that relates to the physical or mental health of the individual, or to provision of health services to the individual. This information might include: information about the registration of the individual for the provision of health services; information about payments or eligibility for health care in respect to the individual; a number, symbol or code assigned to an individual to uniquely identify the individual for health purposes; any information about the individual that is collected in the course of the provision of health services to the individual; information derived from the testing or examination of a body part or bodily substance; identification of a person, e.g. a health professional, as a provider of healthcare to the individual. Good practice requirements are specified for each framework of Informational Consent. Adherence to these requirements is intended to ensure any subject of care and any parties that process personal health information that their agreement to do so has been properly obtained and correctly specified. The Technical Specification is intended to be used to inform:

- **discussion of national or jurisdictional Informational Consent policies;**
- **ways in which individuals and the public are informed about how personal health information is processed within organisations providing health services and health systems;**
- **how to judge the adequacy of the information provided when seeking Informational Consent;**
- **design of both paper and electronic Informational Consent declaration forms; design of those portions of electronic privacy policy services and security services that regulate access to personal health data;**
- **working practices of organisations and personnel who obtain or comply with consent for processing personal health information.**

The Technical Specification does not:

- **address the granting of consent to the delivery of healthcare-related treatment and care. Consent to the delivery of care or treatment has its own specific requirements and is distinct from Informational Consent. Note that as Consent to Treatment and Care are outside the scope of this Technical Specification, the phrase "informational consent" is hereafter supplanted by the shorter "consent". In every case, it is Informational Consent that is intended; specify any jurisdiction's legal requirements or regulations relating to consent. The focus is**

on frameworks, not on jurisdictional legislation or its adequacy in any given jurisdiction. While care has been taken to design the frameworks so that they do not conflict with the legislation in most jurisdictions, they might challenge some existing practices.

This Technical Specification uses an approach that allows organisations or jurisdictions to select a subset of those frameworks which best fit their law culture and approach to data sharing;

- **specify what consent framework is to be applied to a data classification or data purpose as this may vary according to law or policy, although some examples of implementation profiles are provided in an informative Annex;**
- **determine the legal adequacy of the information upon which the consent is based or possible legal consequences of inadequate information;**
- **specify the data format used when consent status is communicated. The focus is on the information characteristics of consent, and not the technology or medium in which the characteristics are instantiated;**
- **specify how individuals giving Informed Consent come to be informed of the responsibilities, obligations and consequences related to granting consent;**
- **specify how individuals are to be informed of the specifics of the data, data sharing or data processing concerned;**
- **specify how consent itself or the specific activities of the consent process are to be recorded; only that they be recorded.**

Specific requirements on recording consent in EHR systems are given in ISO/TS 14441 specify any information security requirements (e.g. the use of encryption or specific forms of user authentication) as these are the subject of other standards (e.g. ISO 27799).

ISO/IEC 29155-4:2016	Systems and software engineering - Information technology project performance benchmarking framework - Part 4: Guidance for data collection and maintenance	WP4, WP6

Description: ISO/IEC 29155-4:2016 provides general requirements and guidance for collecting and maintaining data of information technology (IT) projects and for delivering the benchmarking repository within benchmarking activities of "the IT project performance benchmarking framework" by prescribing the following:

a) requirements and guidance for data element definitions;

b) requirements and guidance for the data collection and maintenance processes within the benchmarking framework;

c) requirements and guidance for maintaining benchmarking repository product and issued benchmarks.

ISO/IEC 29155-4:2016 mainly focuses on three major activities, which are "maintain repository", "submit IT project data", and "measure IT project" activities. ISO/IEC

29155-4:2016 is intended for use by stakeholder(s) of IT project performance benchmarking (e.g. benchmarking user, benchmark provider, benchmarking service provider, and IT project team). **NOTE: The following are examples of how this document can be used:** • **by a benchmark provider, to define data elements, collect and maintain IT project data, and provide benchmarking repository product or issued benchmarks;** • **by a benchmarking analyst, to use benchmarking repository product and/or benchmarks for executing an instance of benchmarking;** • **by a benchmarking service provider, to utilise benchmarking repository product and/or benchmarks for providing benchmarking services;** • **by an IT service provider, to define data elements to be measured and/or to be submitted to repository owner. It is out of the scope of this document to prescribe a specific set of data element definitions, formats or contents of the benchmarking repository.**		
ISO/IEC 27037:2012	Information technology — Security techniques — Guidelines for identification, collection, acquisition and preservation of digital evidence	WP4, WP6
Description: This International Standard provides guidelines for specific activities in handling digital evidence, which are identification, collection, acquisition and preservation of digital evidence that may be of evidential value. This International Standard provides guidance to individuals with respect to common situations encountered throughout the digital evidence handling process and assists organisations in their disciplinary procedures and in facilitating the exchange of potential digital evidence between jurisdictions. This International Standard gives guidance for the following devices and/or functions that are used in various circumstances: **Digital storage media used in standard computers like hard drives, floppy disks, optical and magneto optical disks, data devices with similar functions,** **Mobile phones, Personal Digital Assistants (PDAs), Personal Electronic Devices (PEDs), memory cards,** **Mobile navigation systems,** **Digital still and video cameras (including CCTV),** **Standard computer with network connections,** **Networks based on TCP/IP and other digital protocols, and** **Devices with similar functions as above.** **NOTE 1: The above list of devices is an indicative list and not exhaustive.** **NOTE 2: Circumstances include the above devices that exist in various forms. For example, an automotive system may include mobile navigation system, data storage and sensory system.**		

ISO/IEC 19762:2016	Information technology — Automatic identification and data capture (AIDC) techniques — Harmonized vocabulary	WP4, WP6
Description: ISO/IEC 19762:2016 provides the general terms and definitions in the field of automatic identification techniques and data entry are based on which other specialised sections in various technical fields, as well as the essential terms that must be employed by non-technical users to communicate with specialists in automatic identification and data capture techniques.		
ISO/IEC 38505-1:2017	Information technology — Governance of IT — Governance of data — Part 1: Application of ISO/IEC 38500 to the governance of data	WP4, WP6
Description: ISO/IEC 38505-1:2017 provides guiding principles for members of governing bodies of organisations (which can comprise owners, directors, partners, executive managers, or similar) on the effective, efficient, and acceptable use of data within their organisations by • **applying the governance principles and model of ISO/IEC 38500 to the governance of data,** • **assuring stakeholders that, if the principles and practices proposed by this document are followed, they can have confidence in the organisation's governance of data,** • **informing and guiding governing bodies in the use and protection of data in their organisation, and** • **establishing a vocabulary for the governance of data.** **ISO/IEC 38505-1:2017 can also provide guidance to a wider community, including:** • **executive managers,** • **external businesses or technical specialists, such as legal or accounting specialists, retail or industrial associations, or professional bodies,** • **internal and external service providers (including consultants), and - auditors.** **While this document looks at the governance of data and its use within an organisation, guidance on the implementation arrangement for the effective governance of IT in general is found in ISO/IEC/TS 38501. The constructs in ISO/IEC/TS 38501 can help to identify internal and external factors relating to the governance of IT and help to define beneficial outcomes and identify evidence of success. ISO/IEC 38505-1:2017 applies to the governance of the current and future use of data that is created, collected, stored or controlled by IT systems, and impacts the management processes and decisions relating to data. ISO/IEC 38505-1:2017 defines the governance of data as a subset or domain of the governance of IT, which itself is a subset or domain of organisational, or in the case of a corporation,**		

corporate governance. ISO/IEC 38505-1:2017 is applicable to all organisations, including public and private companies, government entities, and not-for-profit organisations. This document is applicable to organisations of all sizes from the smallest to the largest, regardless of the extent of their dependence on data.		
ISO/IEC 25024:2015	Systems and software engineering — Systems and software Quality Requirements and Evaluation (SQuaRE) — Measurement of data quality	WP4, WP6
Description: ISO/IEC 25024:2015 defines data quality measures for quantitatively measuring the data quality in terms of characteristics defined in ISO/IEC 25012.This International Standard contains the following: • **a basic set of data quality measures for each characteristic;** • **a basic set of target entities to which the quality measures are applied during the data-life-cycle;** • **an explanation of how to apply data quality measures;** • **a guidance for organisations defining their own measures for data quality requirements and evaluation.** **It includes, as informative annexes, a synoptic table of quality measure elements defined in this International standard (Annex A), a table of quality measures associated to each quality measure element and target entity (Annex B), considerations about specific quality measure elements (Annex C), a list of quality measures in alphabetic order (Annex D), and a table of quality measures grouped by characteristics and target entities (Annex E). This International Standard does not define ranges of values of these quality measures to rate levels or grades because these values are defined for each system by its nature depending on the system context and users' needs. This International Standard can be applied to any kind of data retained in a structured format within a computer system used for any kinds of applications. People managing data and services including data are the primary beneficiaries of the quality measures.**		
ISO/IEC 20546:2019	Information technology — Big data — Overview and vocabulary	WP4, WP6
Description: This document provides a set of terms and definitions needed to promote improved communication and understanding of this area. It provides a terminological foundation for big data-related standards. This document provides a conceptual overview of the field of big data, its relationship to other technical areas and standards efforts, and the concepts ascribed to big data that are not new to big data.		
ISO/IEC 18598:2016	Information technology — Automated infrastructure management (AIM) systems — Requirements,	WP4, WP6

	data exchange and applications	
Description: This International Standard specifies the requirements and recommendations for the attributes of automated infrastructure management (AIM) systems. This International Standard explains how AIM systems can contribute to operational efficiency and deliver benefits to **a) cabling infrastructure and connected device administration,** **b) facilities and IT management processes and systems,** **c) other networked management processes and systems (e.g. intelligent building systems),** **d) business information systems covering asset tracking and asset management together with event notifications and alerts that assist with physical network security.** **This International Standard specifies a framework of requirements and recommendations for data exchange with other systems.**		
ISO/IEC 11179-7:2019	Information technology — Metadata registries (MDR) — Part 7: Metamodel for data set registration	WP4, WP6
Description: This document provides a specification for an extension to a Metadata Registry (MDR), as specified in ISO/IEC 11179-3:2013, Clauses 5 to 11 in which metadata which describes data sets, collections of data available for access or download in one or more formats, can be registered. Since a set can contain a single element, this document enables the recording of metadata about a single data value. The registered metadata provides information about the data set that includes the provenance and the quality of the dataset.		
ISO/IEC 20547-3:2020	Information technology — Big data reference architecture — Part 3: Reference architecture	WP4, WP6
Description: This document specifies the big data reference architecture (BDRA). The reference architecture includes concepts and architectural views. The reference architecture specified in this document defines two architectural viewpoints: • **a user view defining roles/sub-roles, their relationships, and types of activities within a big data ecosystem;** • **a functional view defining the architectural layers and the classes of functional components within those layers that implement the activities of the roles/sub-roles within the user view.** **The BDRA is intended to:** • **provide a common language for the various stakeholders;** • **encourage adherence to common standards, specifications, and patterns;**		

• **provide consistency of implementation of technology to solve similar problem sets;** • **facilitate the understanding of the operational intricacies in big data;** • **illustrate and understand the various big data components, processes, and systems, in the context of an overall big data conceptual model;** • **provide a technical reference for government departments, agencies and other consumers to understand, discuss, categorise and compare big data solutions; and** • **facilitate the analysis of candidate standards for interoperability, portability, reusability, and extendibility.**		
ISO/IEC TR 24720:2008	Information technology — Automatic identification and data capture techniques — Guidelines for direct part marking (DPM)	WP4, WP6
Description: This Technical Report describes several methods for applying permanent machine-readable symbols to items – including components, parts and products – using the direct part marking (DPM) methods outlined herein. This Technical Report describes marking methods, marking surface preparation, marking location, protective coatings and other parameters that contribute to the production of quality symbols, but does not specify the information to be encoded.		
ISO/IEC TR 22417:2017	Information technology — Internet of things (IoT) use cases	WP4, WP6
Description: ISO/IEC TR 22417:2017(E) This technical report identifies IoT scenarios and use cases based on real-world applications and requirements. The use cases provide a practical context for considerations on interoperability and standards based on user experience. They also clarify where existing standards can be applied and highlight where standardisation work is needed.		
ISO/IEC TR 20547-2:2018	Information technology — Big data reference architecture — Part 2: Use cases and derived requirements	WP4, WP6
Description: ISO/IEC TR 20547-2:2018 provides examples of big data use cases with application domains and technical considerations derived from the contributed use cases.		
ISO/IEC TR 38505-2:2018	Information technology — Governance of IT — Governance of data — Part 2: Implications of ISO/IEC 38505-1 for data management	WP4, WP6

Description: ISO/IEC TR 38505-2:2018 This document provides guidance to the members of governing bodies of organisations and their executive managers on the implications of ISO/IEC 38505-1 for data management. It assumes understanding of the principles of ISO/IEC 38500 and familiarisation with the data accountability map and associated matrix of considerations, as presented in ISO/IEC 38505-1. This document enables an informed dialogue between the governing body and the senior/executive management team of an organisation to ensure that the data use throughout the organisation aligns with the strategic direction set by the governing body. This document covers the following: • **identifying the information that a governing body requires in order to evaluate and direct the strategies and policies relating to a data-driven business;** • **identifying the capabilities and potential of measurement systems that can be used to monitor the performance of data and its uses.**		
ISO/IEC TR 20943-1:2003	Information technology — Procedures for achieving metadata registry content consistency — Part 1: Data elements	WP4, WP6
Description: An ISO/IEC 11179-based metadata registry (MDR) (hereafter referred to as a "registry") is a tool for the management of shareable data; a comprehensive, authoritative source of reference information about data. It supports the standardisation and harmonisation processes by recording and disseminating data standards, which facilitates data sharing among organisations and users. It provides links to documents that refer to data elements and to information systems where data elements are used. When used in conjunction with an information database, the registry enables users to better understand the information obtained. A registry does not contain data itself. It contains the metadata that is necessary to clearly describe, inventory, analyse, and classify data. It provides an understanding of the meaning, representation, and identification of units of data. The standard identifies the information elements that need to be available for determining the meaning of a data element (DE) to be shared between systems. The purpose of ISO/IEC TR 20943-1:2003 is to describe a set of procedures for the consistent registration of data elements and their attributes in a registry. ISO/IEC TR 20943-1:2003 is not a data entry manual, but a user's guide for conceptualising a data element and its associated metadata items for the purpose of consistently establishing good quality data elements. An organisation may adapt and/or add to these procedures as necessary. The scope of ISO/IEC TR 20943-1:2003 is limited to the associated items of a data element: the data element identifier, names and definitions in different contexts, and examples; data element concept; conceptual domain with its value meanings; and value domain with its permissible values. There is a choice when registering code sets and other value domains in an ISO/IEC 11179 metadata registry. Some Registration Authorities treat these sets as value domains, and others treat them as data elements. For the purposes of ISO/IEC TR 20943-1:2003, the choice will always be to treat the sets as data elements unless explicitly stated. This choice is made to help illustrate the way to register many different kinds of data elements, including examples for registering standard code sets as data elements.		
ISO/IEC TR 23186:2018	Information technology — Cloud computing —	WP4, WP6

	Framework of trust for processing of multi-sourced data	
Description: ISO/IEC TR 23186:2019 This document describes a framework of trust for the processing of multi-sourced data that includes data use obligations and controls, data provenance, chain of custody, security and immutable proof of compliance as elements of the framework.		
ISO/IEC TR 10032:2003	Information technology — Reference Model of Data Management	WP4, WP6
Description: This Technical Report defines the ISO Reference Model of Data Management. It establishes a framework for coordinating the development of existing and future standards for the management of persistent data in information systems. See Annex A for references to existing data management standards. This Technical Report defines common terminology and concepts pertinent to all data held within information systems. Such concepts are used to define more specifically the services provided by data management components, such as database management systems or data dictionary systems. The definition of such related services identifies interfaces which may be the subject of future standardisation. This Technical Report does not specify services and protocols for data management. This Technical Report is neither an implementation specification for systems, nor a basis for appraising the conformance of implementations. The scope of this Technical Report includes processes which are concerned with handling persistent data and their interaction with processes specific to the requirements of a specific information system. This includes common data management services such as those required to define, store, retrieve, update, maintain, backup, restore, and communicate applications and dictionary data. The scope of this Technical Report includes consideration of standards for the management of data located on one or more computer systems, including services for distributed database management. This Technical Report does not include within its scope common services normally provided by an operating system including those processes which are concerned with specific types of physical storage devices, specific techniques for storing data, and specific details of communications and human computer interfaces. A data management standard defines services provided at an interface. It does not impose limitations on how processes are implemented.		
IEC 62974-1:2017	Monitoring and measuring systems used for data collection, gathering and analysis - Part 1: Device requirements	WP4, WP6
Description: IEC 62974-1:2017 specifies product and performance requirements for devices that fall under the heading of "monitoring and measuring systems used for data collection, gathering and analysis", for industrial, commercial and similar use rated below or equal to 1 kV AC and 1,5 kV DC. These devices are fixed and are intended to be used indoors as panel-mounted devices, or as modular devices fixed on a DIN rail, or as housing devices fixed on a DIN rail, or as devices fixed by other means inside a cabinet. These devices are used to upload or download information (energy measured on loads, power metering and monitoring data, temperature		

information…), mainly for energy efficiency purposes. These devices are known as energy servers, energy data loggers, data gateways and I/O data concentrators.		
ASTM E2468:05(2018)	Standard Practice for Metadata to Support Archived Data Management Systems	WP4, WP6
ASTM E2807:11(2019)	Standard Specification for 3D Imaging Data Exchange, Version 1.0	WP4, WP6
Description: This specification describes a data file exchange format for three-dimensional (3D) imaging data, known as the ASTM E57 3D file format, Version 1.0. In this specification, the term "E57 file" is used as a short version of "ASTM E57 3D file format". An E57 file can store 3D point data (those produced by 3D imaging systems), attributes associated with 3D point data (colour and intensity), and 2D imagery (digital photographs obtained using a 3D imaging system). This specification describes all data that will be stored in the file, which is a combination of binary and eXtensible Markup Language (XML) formats.		

3.4.2 IT security

IT security is central to protecting users' integrity and privacy. A series of standards address this but not specifically in relation to welfare technology. In addition, there are standards for identity cards.

Number	Title	Relevant for WP
ISO/IEC 27000:2020	Information technology - Security techniques - Information security management systems - Overview and vocabulary (ISO/IEC 27000:2016)	WP2, WP3, WP7
Description: ISO/IEC 27000:2014 provides the overview of information security management systems (ISMS), and terms and definitions commonly used in the ISMS family of standards. It is applicable to all types and sizes of organisation (e.g. commercial enterprises, government agencies, not-for-profit organisations).		
ISO/IEC 27001:2013	Information technology -- Security techniques -- Information security management systems – Requirements	WP2, WP3, WP7
Description: ISO/IEC 27001:2013 specifies the requirements for establishing, implementing, maintaining and continually improving an information security management system within the context of the organisation. It also includes		

requirements for the assessment and treatment of information security risks tailored to the needs of the organisation. The requirements set out in ISO/IEC 27001:2013 are generic and are intended to be applicable to all organisations, regardless of type, size or nature.		
ISO/IEC 27002:2017	Information technology - Security techniques - Code of practice for information security controls (ISO/IEC 27002:2013 including Cor 1:2014 and Cor 2:2015)	WP2, WP3, WP7
Description: ISO/IEC 27002:2013 gives guidelines for organisational information security standards and information security management practices including the selection, implementation and management of controls taking into consideration the organisation's information security risk environment(s). It is designed to be used by organisations that intend to: 1. select controls within the process of implementing an Information Security Management System based on ISO/IEC 27001; 2. implement commonly accepted information security controls; 3. develop their own information security management guidelines.		
ISO/IEC 27003:2017	Information technology - Security techniques - Information security management systems – Guidance	WP2, WP3, WP7
Description: This document provides explanation and guidance on ISO/IEC 27001:2013.		
ISO/IEC 27004:2016	Information technology - Security techniques - Information security management - Monitoring, measurement, analysis and evaluation	WP2, WP3, WP7
Description: ISO/IEC 27004:2016 provides guidelines intended to assist organisations in evaluating the information security performance and the effectiveness of an information security management system to fulfil the requirements of ISO/IEC 27001:2013, 9.1. It establishes: **a) the monitoring and measurement of information security performance;** **b) the monitoring and measurement of the effectiveness of an information security management system (ISMS) including its processes and controls;** **c) the analysis and evaluation of the results of monitoring and measurement.** **ISO/IEC 27004:2016 is applicable to all types and sizes of organisations.**		
ISO/IEC 27005:2018	Information technology - Security techniques - Information security risk management	WP2, WP3, WP7

Description: ISO/IEC 27005:2018 This document provides guidelines for information security risk management. This document supports the general concepts specified in ISO/IEC 27001 and is designed to assist the satisfactory implementation of information security based on a risk management approach. Knowledge of the concepts, models, processes and terminologies described in ISO/IEC 27001 and ISO/IEC 27002 is important for a complete understanding of this document. This document is applicable to all types of organisations (e.g. commercial enterprises, government agencies, non-profit organisations) which intend to manage risks that can compromise the organisation's information security.		
TLS	Transport Layer Security	WP2, WP3, WP7
Description: Transport Layer Security (TLS) is a series of cryptographic protocols designed to provide communications security over a computer network. Several versions of the protocols find widespread use in applications such as web browsing, email, instant messaging, and voice over IP (VoIP). Websites can use TLS to secure all communications between their servers and web browsers. **The TLS protocol aims primarily to provide privacy and data integrity between two or more communicating computer applications.**		
OAuth		WP2, WP3, WP7
Description: OAuth is an open standard for access delegation, commonly used as a way for Internet users to grant websites or applications access to their information on other websites but without giving them the passwords. This mechanism is used by companies such as Amazon, Google, Facebook, Microsoft and Twitter to permit the users to share information about their accounts with third party applications or websites. **Generally, OAuth provides to clients a "secure delegated access" to server resources on behalf of a resource owner. It specifies a process for resource owners to authorize third-party access to their server resources without sharing their credentials. Designed specifically to work with Hypertext Transfer Protocol (HTTP), OAuth essentially allows access tokens to be issued to third-party clients by an authorisation server, with the approval of the resource owner. The third party then uses the access token to access the protected resources hosted by the resource server.**		
SAML 2.0	Security Assertion Markup Language 2.0	WP2, WP3, WP7
Description: Security Assertion Markup Language 2.0 (SAML 2.0) is a version of the SAML standard for exchanging authentication and authorisation identities between security domains. SAML 2.0 is an XML-based protocol that uses security tokens containing assertions to pass information about a principal (usually an end user) between a SAML authority, named an Identity Provider, and a SAML consumer, named a Service Provider. SAML 2.0 enables web-based, cross-domain single sign-on (SSO), which helps reduce the administrative overhead of distributing multiple authentication tokens to the user. **SAML 2.0 was ratified as an OASIS Standard in March 2005, replacing SAML 1.1. The critical aspects of SAML 2.0 are covered in detail in the official documents SAMLCore, SAMLBind, SAMLProf, and SAMLMeta.**		

WSS	Web Services Security (WS-Security, WSS)	WP2, WP3, WP7
Web Services Security (WS-Security, WSS) is an extension to SOAP to apply security to Web services. It is a member of the Web service specifications and was published by OASIS. **The protocol specifies how integrity and confidentiality can be enforced on messages and allows the communication of various security token formats, such as Security Assertion Markup Language (SAML), Kerberos, and X.509. Its focus is the use of XML Signature and XML Encryption to provide end-to-end security.**		
WS	Web Services Security (WS-Security)	WP2, WP3, WP7
Description: Web Services Security (WS-Security) describes enhancements to SOAP messaging to provide quality of protection through message integrity, message confidentiality, and single message authentication. WS-Security mechanisms can be used to accommodate a wide variety of security models and encryption technologies. **WS-Security is a message-level standard that is based on securing SOAP messages through XML digital signature, confidentiality through XML encryption, and credential propagation through security tokens. The web services security specification defines the facilities for protecting the integrity and confidentiality of a message and provides mechanisms for associating security-related claims with the message.** **WS-Security provides a general-purpose mechanism for associating security tokens with messages. No specific type of security token is required by WS-Security. It is designed to be extensible, for example, to support multiple security token formats.**		
SecureConversation	WS-SecureConversation	WP2, WP3, WP7
Description: WS-SecureConversation is a Web Services specification, created by IBM and others, that works in conjunction with WS-Security, WS-Trust and WS-Policy to allow the creation and sharing of security contexts. Extending the use cases of WS-Security, the purpose of WS-SecureConversation is to establish security contexts for multiple SOAP message exchanges, reducing the overhead of key establishment. **WS-SecureConversation is meant to provide an extensible framework and a flexible syntax, with which one could implement various security mechanisms. It does not by itself guarantee security, but the implementor has to ensure that the result is not vulnerable to any attack.**		

3.4.3 Technology to display users' movements (tracking) and position (routes)

Applies to indoor and outdoor technology – related to defined limits/values so that it can be notified if exceeded. Again, there are no directly relevant current standards but a default that affects the site is:

Number	Title	Relevant for WP
EN ISO 19133:2007	Geographic information — Location-based services — Tracking and navigation (ISO19133:2005)	WP2, WP7
Description: This International Standard describes the data types, and operations associated with those types, for the implementation of tracking and navigation services. This International Standard is designed to specify web services that can be made available to wireless devices through web-resident proxy applications, but is not restricted to that environment.		

Future technology will include new communication solutions, especially machine-to-machine communication for, among other things, wireless transmission of measurement data and services. Here you will find, among other things, solutions for measuring and monitoring various functions, tracking and managing systems. Universal design will be limited to applications where users themselves will apply the technology.

So far, sensors have relied on a local computer on site (e.g. in homes) but technology is now available that communicates directly with the internet through built-in WLAN functionality – using a wireless router for connection. Cloud-based services will make it easier to download services from the internet and will create great opportunities for self-service, broader network access and online resource sharing. In the field of welfare technology, this development may mean that perhaps most services, platforms etc. can be downloaded from the cloud for use, while physical welfare technology in the homes may be limited to sensors, etc. This includes solutions such as wireless sensors, diagnostic systems, body sensors and more.

With increased self-service capabilities, the choice of online services and the like, demands for universal design of the solutions will be important for all users to have equal access to them. To ensure this, standardisation will become a central tool.

3.4.4 Accessibility and ICT

Number	Title	Relevant for WP
EN 301549:2019	Accessibility requirements for ICT products and services	WP2, WP7
Description: The present document specifies the functional accessibility requirements applicable to ICT products and services, together with a description of the test procedures and evaluation methodology for each accessibility requirement in a form that is suitable for use in public procurement within Europe. The present document might be useful for other purposes such as procurement in the private sector. The present document is intended to be used as the basis for an accessible ICT procurement toolkit. The present document will primarily be useful for public procurers to identify the requirements for their purchases, and for manufacturers to employ it within their design, build and quality control procedures. The present document contains the necessary functional requirements and provides a reference		

document such that if procedures are followed by different actors, the results of testing are similar and the interpretation of those results is clear. The test descriptions and evaluation methodology included in the present document are elaborated to a level of detail compliant with ISO/IEC 17007:2009 [i.14], so that conformance testing can give conclusive results. The inherent nature of certain situations makes it impossible to make reliable and definitive statements that accessibility requirements have been met. In those situations therefore, the requirements in the present document are not applicable: - when the product is in a failure, repair or maintenance state where the ordinary set of input or output functions are not available; - during those parts of start-up, shutdown, and other state transitions that can be completed without user interaction. **NOTE 1: Even in the above situations, it is best practice to apply requirements in the present document wherever it is feasible and safe to do so.** **NOTE 2: Compliance issues are covered in normative clause C.1.**		
CEN ISO/TR 22411:2008	Ergonomics data and guidelines for the application of ISO/IEC Guide 71 to products and services to address the needs of older persons and persons with disabilities	WP2, WP7
Description: ISO/TR 22411:2008 presents ergonomics data and guidelines for applying ISO/IEC Guide 71 in addressing the needs of older persons and persons with disabilities in standards development. It provides ergonomics data and knowledge about human abilities — sensory, physical and cognitive — and allergies, as well as guidance on the accessible design of products, services and environments.		
ISO/IEC Guide 71:2014	Guide for addressing accessibility in standards	WP2, WP7
Description: ISO/IEC Guide 71:2014 provides guidance to standards developers on addressing accessibility requirements and recommendations in standards that focus, whether directly or indirectly, on systems (i.e. products, services and built environments) used by people. To assist standards developers to define accessibility requirements and recommendations, it presents a summary of current terminology relating to accessibility, issues to consider in support of accessibility in the standards development process, a set of accessibility goals (used to identify user accessibility needs), descriptions of (and design considerations for) human abilities and characteristics, and strategies for addressing user accessibility needs and design considerations in standards.		

3.4.5 User friendliness

Number	Title	Relevant for WP
ISO 20282-1:2006	Ease of operation of everyday products — Part 1:	WP2, WP7

	Design requirements for context of use and user characteristics	
Description: ISO 20282-1:2006 provides requirements and recommendations for the design of easy-to-operate everyday products, where ease of operation addresses a subset of the concept of usability concerned with the user interface by taking account of the relevant user characteristics and the context of use. ISO 20282-1:2006 is intended to be used in the development of everyday products, for which it defines ease of operation, explains which aspects of the context of use are relevant, and describes the characteristics of the intended user population that may influence usability. The intended users of this part of ISO 20282-1:2006 are usability specialists, ergonomists, product designers, interaction designers, product manufacturers and others involved in the design and development of everyday products. ISO 20282-1:2006 is applicable to mechanical and/or electrical products with an interface that a user can operate directly or remotely to gain access to the functions provided. These products fall into at least one of the following categories: consumer products intended for some or all of the general public which are bought, rented or used, and which may be owned by individuals, public organisations, or private companies; consumer products intended to be acquired and used by an individual for personal rather than professional use (e.g. alarm clocks, electric kettles, telephones, electric drills); walk-up-and-use products that provide a service to the general public (such as ticket-vending machines, photocopying machines, fitness equipment); products used in a work environment, but not as part of professional activities (e.g. a coffee machine in an office); products including software that supports the main goals of use of the product (e.g. a CD player). This part of ISO 20282 is not applicable to the following: purely physical products without an interactive user interface (such as a jug or a hammer); products where appearance or fashion is the main goal (such as a watch with no markings); products requiring specialist training, specific skills and/or professional knowledge (such as a musical instrument or a car); standalone software products; products intended to be used for professional activities only.		
ISO/TS 20282-2:2013	Usability of consumer products and products for public use — Part 2: Summative test method	WP2, WP7
Description: ISO/TS 20282:2013 specifies a user-based summative test method for the measurement of the usability and/or accessibility of consumer products and products for public use (including walk-up-and-use products) for one or more specific user groups. This test method treats accessibility as a special case of usability where the users taking part in the test represent the extremes of the range of characteristics and capabilities within the general user population. When the test method refers to usability, the method can also be used to test accessibility (unless otherwise specified).		

3.5 EU Medical Device Regulation

Upon finalising this report, it is still not clear how the Medical Device Regulation (MDR) will impact the GATEKEEPER project. To make sure partners and pilots have a basis of understanding of the regulation from a standardisation standpoint, an overview is provided here. A comprehensive list of standards relevant to the MDR is provided in Annex A.

Guidance on Clinical Evaluation (MDR) Performance Evaluation (IVDR) of Medical Device Software endorsed in the MDCG: The European Commission provides a range of guidance documents to assist stakeholders in implementing the medical devices regulations.

Legally non-binding guidance documents, adopted by the medical device coordination group (MDCG) in accordance with Article 105 of Regulation 745/2017, pursue the objective of ensuring uniform application of the relevant provisions of the regulations within the EU.

These include:

Ongoing guidance development and other relevant work within MDCG Subgroups (2020) https://ec.europa.eu/health/sites/health/files/md_sector/docs/mdcg_ongoing_guidancedocs_en.pdf

Existing guidance documents

MDCG Position Paper on UDI (Unique Device Identification) assignment for Spectacle lenses & Ready readers https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2020_18_en.pdf

Guidance on application of UDI rules to device-part of products referred to in article 1(8), 1(9) and 1(10) of Regulation 745/2017 (2019) https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2019_2_gui_udi_dev_en.pdf

MDCG guiding principles for issuing entities rules on basic UDI-DI (2019) https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2019_1_budi_rules_ie_en.pdf

Guidance on UDI for systems and procedure packs https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_2018-3-guidance-udi-spp_en.pdf

Guidance on basic UDI-DI and changes to UDI-DI https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_mdcg_2018-1_guidance_udi-di_en.pdf

And other, older, documents.

3.5.1 Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR endorsed by the MDCG

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.

This document file:///C:/Users/Laptop3/Downloads/mdcg_2019_11_guidance_qualification_classification_software.pdf which primarily targets medical software manufacturers, define:

the criteria for the qualification of software falling within the scope of the new medical device regulations and

provides guidance on the application of classification criteria for software under Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR.

The guidance also provides information related to placing on the market.

On software: Medical device software is software that is intended to be used, alone or in combination, for a purpose as specified in the definition of a "medical device" in the MDR or IVDR, regardless of whether the software is independent or driving or influencing the use of a device.

Medical Device Software (MDSW) - Medical device software is software that is intended to be used, alone or in combination, for a purpose as specified in the definition of a "medical device" in the MDR or IVDR, regardless of whether the software is independent or driving or influencing the use of a device.

Software driving or influencing the use of a medical device - is software intended to drive or influence the use of a (hardware) medical device and does not have or perform a medical purpose on its own, nor does it create information on its own for one or more of the medical purposes described in the definition of a medical device or an in vitro diagnostic medical device. This software can, but is not limited to:

- operate, modify the state of, or control the device either through an interface (e.g., software, hardware) or via the operator of this device
- or supply output related to the (hardware) functioning of that device

Decision steps for qualification of software as MDSW

Decision step 1: if the product is software according to Section 2 (Definitions and Abbreviations) of this guidance, then it may be a medical device software, proceed to decision step 2; if the product is not software according to the definition of this guidance, then it is not covered by this guidance but may still be covered by the Medical Devices Regulations.

Decision step 2: if the product is an MDR Annex XVI device, or is an accessory for a medical device, or is software driving or influencing the use of a medical device, then it must be considered as part of that device in its regulatory process or independently if it is an accessory. If it is not, proceed to decision step 3.

Decision step 3: if the software does perform an action on data, or performs an action beyond storage, archival, communication, simple search, lossless compression (i.e. using a compression procedure that allows the exact reconstruction of the original data) then it may be a medical device software (Refer to section 3.1 for more guidance on these software functions) proceed to step 4.

Decision step 4: is the action for the benefit of individual patients? Examples of software which are not considered as being for the benefit of individual patients are those which are intended only to aggregate population data, provide generic diagnostic or treatment pathways (not directed to individual patients), scientific literature, medical atlases, models and templates as well as software intended only for epidemiological studies or registers.

Decision step 5: Is the software medical device software (MDSW) according to the definition of this guidance?

On application of classification criteria for software:

Decision steps for qualification of MDSW as either a medical device or an in vitro diagnostic medical device

Decision Step 1:

Does the Medical Device Software (MDSW) provide information within the scope of the in vitro diagnostic medical device definition? MDSW which provides information according to Regulation (EU) 2017/746 – IVDR Article 2(2) (a) to (f) should qualify as In Vitro Diagnostic Medical Device Software (IVD MDSW)

(a) concerning a physiological or pathological process or state (by investigation of this process or state); or

(b) concerning congenital physical or mental impairments

(c) concerning the predisposition to a medical condition or a disease;

(d) to determine the safety and compatibility with potential recipients;

(e) to predict treatment response or reactions;

(f) to define or monitoring therapeutic measures. A MDSW which falls under the definition set out in EU Article 2 (1) of Regulation (EU) 2017/745 – MDR should qualify as Medical Device Software (MD MDSW). In specific, the following considerations should apply on the provision of information by software on:

(g) diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease

(h) diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,

(i) investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,

(j) control or support of conception;

(k) products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and Annex XVI products.

Decision Step 2:

Does the MDSW create information based on data obtained by in vitro diagnostic medical devices only? If the information provided is based on data obtained solely from in vitro diagnostic medical devices, then the software is an in vitro diagnostic medical device and is therefore an IVD MDSW.

If the data analysed is obtained from a combination of both in vitrodiagnostic medical devices and medical devices, proceed to step 3.

Decision Step 3:

Is the intended purpose substantially driven by data sources coming from in vitro diagnostic medical devices? If yes, then the applicable legislation is Regulation (EU) 2017/746. If the intended purpose is substantially driven by data sources coming from medical devices, then the applicable legislation is Regulation (EU) 2017/745.

In the condition where the intended purpose of the MDSW output data fulfils both the medical device and in vitro diagnostic medical device definitions set out in the MDR and IVDR (refer to Decision step 2), a weighting of the data sources based on the significance of the information in relation to fulfilling the intended purpose should be conducted to aid the manufacturer in determining which regulation to apply.

3.5.2 Transparent Reporting of a Multivariable Prediction Model for Individual Prognosis or Diagnosis (TRIPOD); in anticipation of TRIPOD-ML

Prediction models are developed to aid health care providers in estimating the probability or risk that a specific disease or condition is present (diagnostic models) or that a specific event will occur in the future (prognostic models), to inform their decision making. The Transparent Reporting of a multivariable prediction model for Individual Prognosis Or Diagnosis (TRIPOD) Initiative developed a set of recommendations for the reporting of studies developing, validating, or updating a prediction model, whether for diagnostic or prognostic purposes.

The document: https://bmcmedicine.biomedcentral.com/articles/10.1186/s12916-014-0241-z is a checklist of 22 items, deemed essential for transparent reporting of a prediction model study. The TRIPOD Statement aims to improve the transparency of the reporting of a prediction model study regardless of the study methods used. The TRIPOD Statement is best used in conjunction with the TRIPOD explanation and elaboration document.

The checklist is at the following link: https://bmcmedicine.biomedcentral.com/articles/10.1186/s12916-014-0241-z/tables/1.

3.5.3 Ethics guidelines for trustworthy AI of the High-Level Expert Group on Artificial Intelligence, accompanied by Assessment List for Trustworthy AI (ALTAI) for Self-assessment

These requirements are relevant for products used in the GATEKEEPER project that involve AI.

Trustworthy AI is the operational tool of the Ethics Guidelines for Trustworthy AI, aiming to ensure that users benefit from Artificial Intelligence (AI) without being exposed to unnecessary risks. This list, first presented with the Ethics Guidelines in June 2019, was revised following a piloting process that involved more than 350 stakeholders. The assessment list of the ethics guidelines operationalises the key requirements for ethical AI and offers guidance to implement them in practice. Based on fundamental rights and ethical principles, the updated Guidelines list 7 Key Requirements that AI systems should meet to be Trustworthy and provide an Assessment List to guide the implementation of these requirements in practice. The Key requirements include:

Human agency and oversight Including fundamental rights, human agency, and human oversight.

Technical robustness and safety Including resilience to attack and security, fall back plan and general safety, accuracy, reliability, and reproducibility.

Privacy and data governance Including respect for privacy, quality and integrity of data, and access to data.

Transparency Including traceability, explainability and communication.

Diversity, non-discrimination and fairness Including the avoidance of unfair bias, accessibility and universal design, and stakeholder participation.

Societal and environmental wellbeing Including sustainability and environmental friendliness, social impact, society, and democracy.

Accountability Including auditability, minimisation and reporting of negative impact, trade-offs, and redress.

Details can be found at https://ec.europa.eu/futurium/en/ai-alliance-consultation/guidelines/1#top.

3.5.4 OAuth 2.0

OAuth 2.0 is the industry-standard protocol for authorisation. OAuth 2.0 focuses on client developer simplicity while providing specific authorisation flows for web applications, desktop applications, mobile phones, and living room devices. OAuth 2 is then an authorisation framework that enables applications to obtain limited access to user accounts on an HTTP service, such as Facebook, GitHub, and DigitalOcean. OAuth 2 provides authorisation flows for web and desktop applications, and mobile devices.

OAuth defines four roles:

- Resource Owner
- Client
- Resource Server
- Authorisation Server

The resource owner is the user who authorises an application to access their account. The application's access to the user's account is limited to the "scope" of the authorisation granted (e.g. read or write access).

The resource server (API) hosts the protected user accounts, and the authorization server verifies the identity of the user then issues access tokens to the application.

The client is the application that wants to access the user's account. Before it may do so, it must be authorized by the user, and the authorisation must be validated by the API.

Their relationship is that:

The *application* requests authorisation to access service resources from the *user;*

If the *user* authorised the request, the *application* receives an authorization grant;

The *application* requests an access token from the *authorisation server* (API) by presenting authentication of its own identity, and the authorization grant;

If the application identity is authenticated and the authorisation grant is valid, the *authorisation server* (API) issues an access token to the application. Authorisation is complete.

The *application* requests the resource from the *resource server* (API) and presents the access token for authentication;

If the access token is valid, the *resource server* (API) serves the resource to the *application.*

The actual flow of this process will differ depending on the authorisation grant type in use.

See also: https://oauth.net/2/.

4 Gap analysis

4.1 Introduction

The objective of WP8 T8.1 is that "a preliminary analysis will be conducted in respect to existing and on-going standardisation relating to the requirements for age friendly environments, and the relevant standardisation committees and organisations". Furthermore to "exploit experience" and knowledge gathered through the project implementation and the realisation of the pilots to support new working groups for standards and enable new roadmaps linking WoT, FHIR and other standards towards the better interoperability of health and IoT based smart environments.

Based on the overview of standards, there is good coverage of different standards in the various fields relevant for the GATEKEEPER project. In this chapter we will endeavour to identify the needs for standards based on the interests and experiences of the pilots that are part of the project and draw some conclusions for possible gaps in the current selection of standards.

4.2 The pilots' needs regarding standards

The following are the pilots involved in the GATEKEEPER project:

- Pilot 1 Aragon
- Pilot 2 Basque Country
- Pilot 3 Cyprus
- Pilot 4 Greece
- Pilot 5 Milton Keynes
- Pilot 6 Puglia
- Pilot 7 Poland
- Pilot 8 Saxony

Pilot	Stated need standards	Stated need technology
Pilot 1 Aragon	FHIR (pending technology providers)	MC, LC and HC, might depend on technology selected.
Pilot 2 Basque Country		Patient app or wearables, dashboard for data analysis, electronic pill dispenser, digital coach/virtual assistant, smartwatches
Pilot 3 Cyprus	FHIR	Smartwatches, tablets (Samsung), web-based platform, secure storage
Pilot 4 Greece	FHIR	Will decide on specific devices. Blood pressure meter, blood glucose meter, AI assistant, visual analytics platform,

		diabetes management platform, localised nutrition platform
Pilot 5 Milton Keynes		ActiveAge app, Samsung watch, Samsung smart doorlock, Samsung watch, Tiago robot
Pilot 6 Puglia	FHIR (pending technology providers)	DMCoach technology, new technology may be available pending Covid 19 induced strategy for Regional telemedicine deployment, DM Coach technology
Pilot 7 Poland	Electronic Health Records	Adherence monitors
Pilot 8 Saxony	FHIR (pending technology providers)	Samsung devices, smartwatches, smartphones, movement and fall sensors, home sensors and possibly home devices, web-based platform, secure storage

The overview shows that the main needs of standards will concentrate on medical equipment and monitoring standards, besides data collection and communication related standards.

In addition, the GATEKEEPER project refers to the basic importance of W3C Web of Things WoT standards, and that the GK will be a contribution to this through building a domain standardisation with WoT in the healthcare domain through the FHIR standard (healthcare information exchange, see below) and the SAREF ontology (matching of existing assets like standards, protocols and data models/etc. in the smart (home) appliances domain, see below) – and build GATEKEEPER IoT environment with maximum compliance with existing open standards. This will be dealt with in T8.2.

4.3 Comment on the standards referred by pilots

FHIR standard - is a healthcare information exchange standard that makes use of an HL7-defined set of "resources" to support information sharing by a variety of means, including documents, messages, services and RESTful interfaces. FHIR defines resources for clinical and administrative content (e.g. Observation, Patient, etc.) as well as resources for "infrastructure" purposes. Some of these infrastructure resources are used to define the standard itself – i.e. what the characteristics of resources are, what codes can be used in them, etc. This set of infrastructure resources is referred to as the "Conformance resources". The complete list of them can be found here: http://build.fhir.org/conformance-module.html

SAREF ontology - The Smart Appliances REFerence (SAREF) ontology is a shared model of consensus that facilitates the matching of existing assets (standards/protocols/datamodels/etc.) in the smart appliances domain. The SAREF ontology provides building blocks that allow separation and recombination of different parts of the ontology depending on specific needs. Complete description here: https://sites.google.com/site/smartappliancesproject/ontologies/reference-ontology.

4.4 Relevant technology stated in Work Packages

Work Package	Relevant technology
WP1	Management of data
WP2	Management of data
WP3	Technology inventory (D3.4)
WP4	Data management
WP5	AI Integration system
WP6	eHealth technology, medical devices, AI
WP7	Data management, eHealth technology, medical devices, AI
WP8	Not relevant
WP9	Middle layer service APIs, AI service products

These responses highlight that the standardisation needs of the individual work packages will thus seem to concentrate on:

- Data management
- Data protection
- AI integration systems
- eHealth technology
- medical equipment

Referring to part one of the T8.1 with overview of existing standards, many of these areas are covered by different types of standards.

4.5 Possible new standardisation initiatives

Based on the overview of existing standards and the need to cover the areas being part of the GATEKEEPER project, some possible initiatives for standardisation that can fulfil the need for standards that can strengthen the outcomes of the GATEKEEPER project can be proposed. These are to be followed up in WP8, T8.2. Where needed, it will propose new and specific work items to be standardised.

4.5.1 Additional standard to focus on accessibility aspects of welfare technology

- Topics include:
  - Definition and overview of welfare technology
  - Ensuring that technical solutions, including hardware and software are accessible for all, for example hardware for environment control, like remote controls, computers etc., software to follow accessibility requirements
  - Accessible solutions for technical communications, social alarms and IT security
  - Accessible formats for information
  - Technology to function in emergency situations
  - Technology from use by specialists to use by end-users
  - Connecting requirements for accessible housing and the technology to be installed for dwellers with special needs for adaptation etc.

4.5.2 Additional home appliances standard

- This may include quite different issues like user interface, sensor technology, microelectronics, software, the Internet and networking technology, energy, control- and monitoring technology and robotics. There are several technologic possibilities for the care sector being relevant for welfare technology:
  - Robots
    - House robots
    - Robot assistants
    - Robots for social stimulation
    - Rehabilitation robots
  - Smart house technology
    - Communication, information exchange and digital assistants
    - Video communication
    - Web based advisory services
    - Digital user assistants
  - Positioning and orientation technology
    - Outdoor positioning with GPS
  - Medical and health related monitoring
    - Sensors in napkins, clothes and bed
    - Sensor systems carried on person
    - Urine- and blood samples
    - Electronic medicine cabinets and pillboxes

  Additional proposals for standards based on the needs of pilots will be added after these have been implemented and experience gathered.

4.5.3 Additional standard on data security concerning health monitoring

Health monitoring is an important part of GATEKEEPER project to digitalise, record and analyse users as part of the pilots, and including data sharing, for the benefit of medical care. However, this also involves issues of user privacy and ethical implications.
A standard can introduce requirements to avoid that personal health monitoring can worry users because of the introduction of "third parties" into their private spaces and of someone making decisions on their behalf. Personal health monitoring systems can:

- be implemented to monitor the users' sensitive domains;
- be presented in a way that users don't understand the systems' potential, in terms of violations of privacy and data mining;
- be collecting and presenting data in formats that can be in distressing or revealing formats in the eyes of the users;
- can lead to data having secondary uses unforeseen by the users and thus violate their privacy.

A standard should therefore deal with requirements to system for personal health monitoring based on background normative theories of privacy, autonomy and self-determination, and to improve the development and governance of data use in health monitoring.

4.6 Updated GAP analysis based on continuous discussions with pilots and technical partners in 2021

For the updated gap analysis, we have gathered and analysed information provided by pilot and technical partners throughout the project since the submission of the first version of the deliverable. During M19-21 these efforts have intensified, including bilateral meetings, surveys and joint workshops also covering topics from T8.2 and T8.3.

From our investigation of the needs of GATEKEEPER pilots and technical partners, we have further investigated existing standards and potential gaps when it comes to:

- Mobile applications used in medical treatment, such as smart phones and smart watches, data processing, medical devices and secure transportation of information between doctors;
- Open API (publicly available application programming interface that provides developers with programmatic access to a proprietary software application or web service) and relations to web of Things in GATEKEEPER – Web of things have more extensive descriptions.
- Ethics and data issues;
- Data process modelling and relation to GDPR;
- Testing environment for data in relation to GDPR;
- Process modelling of the intervention and protocols for cases of cardiovascular disease and hypertension in the pilot sites.

We will in the following look at which standards already exist and where there is a gap.

4.6.1 Mobile applications used in medical treatment

In this field the following standards are deemed to be relevant to the GATEKEEPER project:

Number	Title	Description
ISO/TR 17522:2015	Health informatics — Provisions for health applications on mobile/smart devices	This Technical Report is applicable to the development of smart health applications available anywhere, anytime and supporting new health businesses based on the smart devices. This Technical Report is to investigate the areas of ongoing developments and analyses of emerging interoperability standards for smart mobile devices.
ISO/IEC TR 30125:2016	Information technology — Biometrics used with mobile devices	This Technical Report provides guidance for developing a consistent and secure method of biometric (either alone or supported by non-biometric) personalisation and authentication in a mobile environment for systems procured on the open market. Guidance is provided for 1:1 verification or 1:few positive identification; biometric sample capture in the mobile environment where conditions are not well controlled and not covered in ISO/IEC Biometric interchange format standards and the ISO/IEC Biometric sample quality Technical Reports; NOTE 1: Further information regarding architectures may be found in NIST/SP 500-288. the best use of multiple biometric and non-biometric (PINs, passwords, personal data) personalisation and authentication methods (i.e. multifactor). NOTE 2: More information may be found in ISO/IEC 30108-1. This Technical Report defines a framework to address methods and approaches for remote and

		unsupervised enrolment, together with secure storage and transmission of biometric and supporting biographic data, covering a variety of both online connected and offline modes. This Technical Report identifies the functional elements and components of a generic mobile biometric system and the distinct characteristics of each component. It provides guidance related to a generic mobile architecture with reference to supporting standards. The context recognises a) the user as being mobile and b) operation across a variety of platforms, particularly mobile devices but also including tablet, laptop and other personal computing devices. The key to defining this context is whether the user's environment is physically controlled by the organisation to which the user seeks access.
BS PD ISO/TR 17522:2015	Health informatics. Provisions for health applications on mobile/smart device	BS PD ISO/TR 17522:2015 is applicable to the development of smart health applications available anywhere, anytime and supporting new health businesses based on the smart devices. This Technical Report is to investigate the areas of ongoing developments and analyses of emerging interoperability standards for smart mobile devices. Cross References: ISO 11073-90101:2008 ISO 11073-92001:2007 ISO 13606-1:2008 ISO 13606-2:2008 ISO 13606-3:2009 ISO/TS 13606-4:2009 ISO 13606-5:2010 ISO 18232:2006 ISO 27789:2013 ISO/IEC 646:1991 ISO/IEC 15417:2007 ISO/IEC 15420:2009 ISO/IEC 15424:2008 ISO/IEC 16022:2006 ISO/IEC 18004 ISO/IEC 27001:2013 ISO/TS 22220:2011 ISO/TS 27527:2010

		ISO/TR 16056-1:2004 ISO/TR 16056-2:2004 ISO/TR 27809:2007 ISO/IEEE 11073-10404:2010 ISO/IEEE 11073-10407:2010 ISO/IEEE 11073-10408:2010 ISO/IEEE 11073-10415:2010 ISO/IEEE 11073-10417:2014 ISO/IEEE 11073-10471:2010 ISO/IEEE 11073:2010 ISO/IEEE 11073:2006 ISO/HL7 21731:2006 ISO/HL7 27931:2009 ISO/HL7 27932:2009 All current amendments available at time of purchase are included with the purchase of this document.
ISO/IEC TR 23188:2020	Information technology — Cloud computing — Edge computing landscape	This is about the concept of edge computing, its relationship to cloud computing and IoT, and the technologies that are key to the implementation of edge computing. The topics are the concept of edge computing systems; the architectural foundation of edge computing; edge computing terminology; software classifications in edge computing, e.g. firmware, services, applications; supporting technologies, e.g. containers, serverless computing, microservices; networking for edge systems, including virtual networks; data, e.g. data flow, data storage, data processing; management, of software, of data and of networks, resources, quality of service; virtual placement of software and data, and metadata; real time; and mobile edge computing as well as mobile devices.
ISO/IEC 24755:2007	Information technology — Screen icons and symbols for personal mobile communication devices	This International Standard defines a consistent set of screen icons and symbols – together with their related functions – that are presented by personal mobile communications devices (e.g. mobile phones and personal digital assistants). These devices have an accessible touch

		screen operated using a stylus pen or finger, or button access with personalised application, that users interact with to control the information presented by these devices. This International Standard provides a consistent set of icon graphics for using personal information of management-related applications and controlling the device. These icons and symbols represent typical functions and statuses by their association with conventional controls and functions on real world objects. This International Standard applies to all icon graphics displayed with resolution of 32 × 32 pixels or higher. The graphic presentation can be either dynamic or fixed.
ISO 29283:2011	ITS CALM Mobile Wireless Broadband applications using Communications in accordance with IEEE 802.20	ISO 29283:2011 specifies the options appropriate for CALM using mobile wireless broadband (MWB) techniques conforming to the IEEE 802.20 air interface and protocol specification recommended by ITU-R M.1801, and specifies the management interface requirements. CALM links are required for quasi-continuous, prolonged and short duration communications between vehicles and the roadside, between vehicles, and between mobile equipment and fixed infrastructure points, over medium and long ranges. Wherever practicable, ISO 29283:2011 has been developed by reference to suitable extant standards, adopted by selection. Required regional variations are provided. Application specific upper layers are not included in ISO 29283:2011, but will be driven by application standards.
BS 09/30188977 DC	BS ISO 29283. ITS CALM Mobile Wireless Broadband applications using Communications in	Computer networks, Traffic control, Road vehicles, Interfaces (data processing), Open systems interconnection, Radiocommunication, Mobile communication systems, Data

	accordance with IEEE 802.20	link layer (OSI), Data processing, Communication networks, Data transmission, Road transport, Telecommunication systems, Broadband networks, Local area networks

The overview shows that a few standards exist that are relevant for the requested area of mobile applications used in medical treatment. However, this is a field that needs to be developed focusing on the health areas and medical equipment covered by the GATEKEEPER project. There is also a need to have an overview of the requirements for the universal design of mobile applications in EN 301549.

4.6.2 Open API

In this field, the following standards are deemed to be relevant to the GATEKEEPER project:

Number	Title	Description
ISO/IEC TR 13066-6:2014	Information technology — Interoperability with Assistive Technology (AT) — Part 6: Java accessibility application programming interface (API)	Standardisation in the field of user-system interfaces in information and communication technology (ICT) environments and support for these interfaces to serve all users, including people having accessibility or other specific needs, with a priority
ISO/IEC 19784-1:2018	Information technology - Biometric application programming interface - Part 1: BioAPI specification	Identification methods, Interfaces (data processing), Data processing, Human body, Biometrics, Application programme interface, Data representation, Information exchange
ISO/IEC TR 24030:2021	Information technology — Artificial Intelligence (AI) — Use cases	Standardisation in the area of Artificial Intelligence. Serve as the focus and proponent for JTC 1's standardisation programme on Artificial Intelligence. Provide guidance to JTC 1, IEC, and ISO committees developing
ISO/IEC TR 13066-4:2015	Information technology — Interoperability with assistive technology (AT) — Part 4: Linux/UNIX graphical environments accessibility API	This part of ISO/IEC 13066 provides an overview to the structure and terminology of the Linux/UNIX graphical environments accessibility API. It will provide the following:

		a description of the overall architecture and terminology of the API; further introductory explanations regarding the content and use of the API beyond those found in ISO/IEC 13066-1:2011, Annex A provides an overview of the main properties, including list of user interface elements, of how to get and set focus, and of communication mechanisms in the API; a discussion of design considerations for the API (e.g. pointers to external sources of information on accessibility guidance related to using the API information on extending the API (and where this is appropriate); an introduction to the programming interface of the API (including pointers to external sources of information). It will provide this information as an introduction to the Java API to assist the following: IT system level developers who create custom controls and/or interface to them; AT developers involved in programming "hardware to software" and "software to software" interactions.
ISO/IEC TR 13066-2:2016	Information technology — Interoperability with Assistive Technology (AT) — Part 2: Windows accessibility application programming interface (API)	This part of ISO/IEC 13066 specifies services provided in the Microsoft Windows platform to enable assistive technologies (AT) to interact with other software. One goal of this part of ISO/IEC 13066 is to define a set of application programming interfaces (APIs) for allowing software applications to enable accessible technologies on the Microsoft Windows platform. Another goal of this part of ISO/IEC 13066 is to facilitate extensibility and interoperability by enabling

		implementations by multiple vendors on multiple platforms. This part of ISO/IEC 13066 is applicable to the broad range of ergonomics and how they apply to human interaction with software systems.

From the research carried out, in the field of medicine and medical equipment there is a gap relating to API related themes in standardisation, with the exception of Assistive Technology.

4.6.3 Ethics and data issues

In this field the following standards are deemed to be relevant to the GATEKEEPER project:

Number	Title	Description
CAN/CGSB 191.1-2013	Research ethics oversight of biomedical clinical trials	This National Standard of Canada applies to Research Ethics Boards (REBs) that evaluate applications for ethical acceptability. If an REB grants ethics approval to conduct biomedical clinical trials, it will provide research ethics oversight of biomedical clinical trials that are subject to the Food and Drugs Act and applicable Regulations (see 2.1). This Standard does not preclude or override any applicable regulatory or legal requirement. Intended users: This Standard is intended for use primarily by REB chairs, members and administrative staff, qualified investigators and study teams conducting biomedical clinical trials, sponsors and funders of biomedical clinical trials, those with responsibility for establishing and ensuring effective REB operations, those with responsibility for research

		ethics oversight of biomedical clinical trials in organisations where they are conducted, and regulatory authorities that evaluate REBs with research ethics oversight of biomedical clinical trials. An organisation with an REB intending to use this Standard will take responsible measures to ensure that the roles and responsibilities of the REB are defined, resources are made available, and processes are in place for research ethics oversight of biomedical clinical trials conducted under its auspices, to ensure that the REB meets the requirements of this Standard and applicable statutory and regulatory requirements.
EN 16686:2015	Osteopathic healthcare provision	This European Standard specifies the requirements and recommendations regarding the healthcare provision, facilities and equipment, education, and ethical framework for the good practice of osteopathy.
EN 14485:2003	Health informatics - Guidance for handling personal health data in international applications in the context of the EU data protection directive	This European Standard provides guidance on data protection for those involved in international informatics applications which entail transmission of person health data from an EU Member State to a non-EU Member State. Its purpose is to assist in the application of the EU Directive on Data Protection

EN 16844:2017+A2:2019	Aesthetic medicine services - Non-surgical medical treatments	Medical equipment, Technical documents, Hazards, Marking, Packaging, Safety measures, Symbols, Definitions, Handbooks, Instructions for use, Medical instruments, Identification methods, Sterile equipment, Consumer-supplier relations, Documents, Implants (surgical)
ISO/TR 22221:2006	Health informatics - Good principles and practices for a clinical data warehouse	Health services, Data processing, Systems analysis, Clinical medicine, Medical technology, Data security, Data handling, Data management, Data representation, Databases, Maintenance, Organisations
CR 13694:1999	Health Informatics - Safety and Security Related Software Quality Standards for Healthcare (SSQS)	Temperature measurement, Optics, Performance testing, Power output, Equations, Energy transfer, Reports, Lasers, Noise (spurious signals), Calibration, Optical instruments, Statistical distribution, Density, Error correction, Test equipment
ISO 22600-1:2014	Health informatics — Privilege management and access control — Part 1: Overview and policy management	This multi-part International Standard defines principles and specifies services needed for managing privileges and access control to data and/or functions. It focuses on communication and use of health information distributed across policy domain boundaries. This includes healthcare information sharing across unaffiliated providers of healthcare, healthcare organisations,

		health insurance companies, their patients, staff members, and trading partners by both individuals and application systems ranging from a local situation to a regional or even national situation. It specifies the necessary component-based concepts and is intended to support their technical implementation. It will not specify the use of these concepts such as clinical process pathways. This part of ISO 22600 proposes a template for the policy agreement. It enables the comparable documentation from all parties involved in the information exchange. This part of ISO 22600 excludes platform-specific and implementation details. It does not specify technical communication services and protocols which have been established in other standards. It also excludes authentication techniques.
EN ISO 15189:2012	Medical laboratories - Requirements for quality and competence (ISO 15189:2012, Corrected version 2014-08-15)	Medical laboratory services are essential to patient care and therefore must meet the needs of all patients and the clinical personnel responsible for their care. To help achieve this, BSI has developed BS EN ISO 15189:2012 Medical laboratories - Requirements for quality and competence which specifies the needs for quality and competence within medical laboratories. This International Standard can be applied by medical

		laboratories to develop their quality management systems whilst assessing their own competence. It can also be used for recognising the proficiency of medical laboratories by customers, regulating authorities and accreditation bodies. BS EN ISO 15189:2012 is intended for use throughout the currently recognised disciplines of medical laboratory services, those working in other services and disciplines such as clinical physiology, medical imaging and medical physics may also find it useful. In addition, bodies engaged in the recognition of the competence of medical laboratories will be able to use this International Standard as the basis for their activities. The standard offers insight into the arrangements for: Examination requests Patient preparation & identification Collection of samples Transportation storage Safety & ethics in medical laboratory work. It is acknowledged that a country could have its own specific regulations or requirements applicable to some or all its professional personnel and their activities and responsibilities in this domain.

		Whilst this International Standard is not intended to be used for the purposes of certification; a medical laboratory's fulfilment of the requirements of this International Standard means the laboratory meets both the technical competence requirements and the management system requirements that are necessary for it to consistently deliver technically valid results.
ISO/HL7 10781:2015	Health Informatics — HL7 Electronic Health Records-System Functional Model, Release 2 (EHR FM)	Personal health, Records (documents), Data transmission, Health services, Information exchange, Data storage, Medical sciences, Computer applications, Data representation, Data handling, Data processing, Data transfer
ISO/TS 21547:2010	Health informatics — Security requirements for archiving of electronic health records — Principles	The purpose of this Technical Specification is to define the basic principles needed to securely preserve health records in any format for the long term. It concentrates on previously documented healthcare-specific archiving problems. It also gives a brief introduction to general archiving principles. Unlike the traditional approach to standardisation work, where the perspective is that of modelling, code sets and messages, this Technical Specification looks at archiving from the angle of document management and related privacy protection. The document management

		angle has traditionally been used in connection with patient records in paper form and it can also be applied to digitally stored documents. There are different architectural and technical ways to develop and implement long-term preservation of electronic health records. Archiving can be a function of the online record-keeping system, and we can have a separate independent archive or a federated one. Electronic health records are, in many cases, archived in the form of documents, but other technical solutions also exist. In this Technical Specification archiving is understood to be a wider process than just the permanent preservation of selected records. Archiving of EHRs is a holistic process covering records maintenance, retention, disclosure and destruction when the record is not in active use. Archiving also includes tasks the EHR system should perform before the record is sent to the EHR-archive. This Technical Specification defines architecture and technology-independent security requirements for the long-term preservation of EHRs having fixed content. This Technical Specification and a complementary Technical Report, ISO/TR 21548, concentrate on the security requirements (integrity, confidentiality, availability and

		accountability) necessary for ensuring adequate protection of health information in long-term digital preservation. This Technical Specification will also address privacy protection requirements for both the EHR and eArchiving systems used in the healthcare environment. This Technical Specification defines functional security requirements for long-term archiving of EHRs, but the practical archiving models and technology required are outside the concept of this Technical Specification. It is also outside of the Scope of this Technical Specification to comment on the following. The creation, management and storage of active health records (records which can be modified, updated and accessed any time at the level of a single object or item) inside the EHR-system. However, this Technical Specification defines responsibilities and tasks the EHR-system should undertake before it transfers an EHR to the electronic archive. The content of information submission packets sent to the EHR-archive. However, this Technical Specification defines security requirements for those packets. Any storage structures used (such as DICOM, HL7 or XML) or metafile descriptions used (such as Dublin core or HL7 CDA header) in the eArchiving process.

		Implementation of security services such as PKI, electronic signatures, etc. Any of the storage times of EHRs or media applicable for their storage; rather, these will continue to be provided in accordance with national legislation.

In this area there is quite a broad choice of relevant standards that can be used as a reference for the pilot work in the GATEKEEPER project.

4.6.4 Data process modelling and relation to GDPR

In this field the following standards are deemed to be relevant to the GATEKEEPER project:

Number	Title	Description
ISO/IEC 15944-12:2020	Information technology. Business operational view. Privacy protection requirements (PPR) on information life cycle management (ILCM) and EDI of personal information (PI)	This document: provides method(s) for identifying, in Open-edi modelling technologies and development of scenarios, the additional requirements in business operational view (BOV) specifications for identifying the additional external constraints to be applied to recorded information in business transactions relating to personal information of an individual, as required by legal and regulatory requirements of applicable jurisdictional domains; integrates existing normative elements in support of privacy and data protection requirements as are already identified in ISO/IEC 14662 and ISO/IEC 15944-1 , ISO/IEC 15944-2 , ISO/IEC 15944-4 ,

		ISO/IEC 15944-5 , ISO/IEC 15944-8 , ISO/IEC 15944-9 , and ISO/IEC 15944-10; provides overarching, operational 'best practice' statements for associated (and not necessarily automated) processes, procedures, practices and governance requirements that act in support of implementing and enforcing technical mechanisms which support the privacy/data protection requirements necessary for implementation in Open-edi transaction environments; focuses on the life cycle management of personal information i.e., the contents of SPIs (and their SRIs) related to the business transaction interchanged via EDI as information bundles and their associated semantic components among the parties to a business transaction. NOTE: Privacy protection requirements (PPR) on information life cycle management (ILCM) and EDI of personal information as stated in this document serve as a minimum set of ILCM policy and operational requirements for all recorded information pertaining to a business transaction, as well as ILCM implementation in any organisation in general. This document does not specify the technical mechanisms, i.e., functional

		support services (FSV) which are required to support BOV-identified requirements. Detailed exclusions to the scope of this document are provided in Annex H.
EN IEC 31010:2019	Risk management - Risk assessment techniques	What is a tracked changes standard? A tracked changes version of a Standard indicates the changes made, during the standards revision process, between the active standard and its previous version. Additions, deletions, and other formatting and/or content revisions are clearly displayed as underlined and strikethrough texts, ensuring all changes made between the two documents are quickly and easily identified. This version of the standard includes both a copy of the new standard, along with a track changes version. What is this standard about? It gives guidance on how to select and apply risk assessment techniques in a wide range of contexts. These techniques will help users make decisions where there's uncertainty and provide information about specific risks as part of a risk management process. The standard summarises a range of techniques and references other documents where these techniques are described in more detail. Who is this standard for?

		Risk managers and organisations required to conduct risk assessments for compliance or conformance purposes. In addition, it will be useful to: Anyone involved in assessing risk People involved in developing guidance setting out how risk is to be assessed in specific contexts People who need to make decisions where there is uncertainty including those who: – Commission or evaluate risk assessments – Need to understand the outcomes of assessments – Have to choose assessment techniques to meet specific needs Why should you use this standard? It gives guidance on the selection and application of various techniques that can be used to help improve the way uncertainty is considered and to help understand risk. It works as an introduction to selected techniques and compares their possible applications, benefits, and limitations. It also provides references to sources of more detailed information. NOTE 1: While this standard discusses and provides example techniques, the techniques described are non-

		exhaustive and no recommendation is made as to the efficacy of any given technique in any given circumstance. Care should be taken in selecting any technique to ensure that it is appropriate reliable and effective in the given circumstance. NOTE 2: Good management practices should be followed throughout and are not repeated in this standard. What's changed since the last update? This standard is a technical revision which replaces EN 31010:2010 Risk management - Risk assessment techniques. It includes the following significant technical changes: More detail is given on the process of planning, implementing, verifying and validating the use of the techniques The number and range of application of the techniques has been increased The concepts covered in ISO 31000 Risk management (which is a normative document) are no longer repeated in this standard

In this field, there is a limited number of standards that are relevant to the health area. It would therefore appear that there is a gap in the available standardisation issues which can be focused on in the GATEKEEPER project.

4.6.5 Testing environment for data in relation to GDPR

In this field the following standards are deemed to be relevant to the GATEKEEPER project:

Number	Title	Description
ISO/IEC TR 29119-11:2020	Software and systems engineering. Software testing. Guidelines on the testing of AI-based systems	This document provides an introduction to AI-based systems. These systems are typically complex (e.g. deep neural nets), are sometimes based on big data, can be poorly specified and can be non-deterministic, which creates new challenges and opportunities for testing them. This document explains those characteristics which are specific to AI-based systems and explains the corresponding difficulties of specifying the acceptance criteria for such systems. This document presents the challenges of testing AI-based systems, the main challenge being the test oracle problem, whereby testers find it difficult to determine expected results for testing and therefore whether tests have passed or failed. It covers testing of these systems across the life cycle and gives guidelines on how AI-based systems in general can be tested using black-box approaches and introduces white-box testing specifically for neural networks. It describes options for the test environments and test

		scenarios used for testing AI-based systems. In this document an AI-based system is a system that includes at least one AI component.
ISO/IEC 20547-4:2020	Information technology. Big data reference architecture. Security and privacy	This document specifies the security and privacy aspects applicable to the big data reference architecture (BDRA) including the big data roles, activities and functional components and provides guidance on security and privacy operations for big data.

In this field there is a limited number of standards that are relevant particularly for the health area. It would therefore appear that there is a gap in the available standardisation issues which can be focused upon in the GATEKEEPER project.

4.6.6 Process modelling of the intervention and protocols for cases of cardiovascular disease and hypertension in the pilot sites

In this field there seems to be none or very few standards relevant to the GATEKEEPER project. One, the ISO/TS 20225:2001 Global medical device nomenclature for the purpose of regulatory data exchange, has been withdrawn.

In addition, two areas are also relevant:

- Create binding templates of FHIR on Web of Things
  No directly relevant standards are identified in this field.

- Provide interoperability on semantic contexts between web of Things and Open Api.

  In this field, the following standards are deemed to be relevant to the GATEKEEPER project:

Number	Title	Description
ISO/IEC 30141:2018	Internet of Things (IoT) — Reference Architecture	This document specifies a general IoT Reference Architecture in terms of defining system characteristics, a

		Conceptual Model, a Reference Model and architecture views for IoT.
ISO/IEC TR 20547-2:2018	Information technology — Big data reference architecture — Part 2: Use cases and derived requirements	Communication technology, Management, Computer software, Organisations, Performance, Employers, Personnel, Computer hardware, Conformity, Risk assessment, Enterprises, Data processing
ISO/IEEE 11073-10101:2020	Health informatics — Device interoperability — Part 10101: Point-of-care medical device communication — Nomenclature	Standardisation in the field of health informatics, to facilitate capture, interchange and use of health-related data, information, and knowledge to support and enable all aspects of the health system.
ISO/TS 21089:2018	Health informatics — Trusted end-to-end information flows	This document describes trusted end-to-end flow for health information and health data/record management. Health data is originated and retained, typically as discrete record entries within a trusted electronic health record (EHR), personal health record (PHR) or other system/device. Health data can include clinical genomics information. Health record entries have a lifespan (period of time managed by one or more systems) and within that lifespan, various lifecycle events starting with “originate/retain”. Subsequent record lifecycle events may include “update”, “attest”, “disclose”, “transmit”, “receive”, “access/view” and more. A record entry instance is managed – over its lifespan – by the source system. If record entry content is exchanged, this instance may also be managed intact by one or more downstream systems.

		Consistent, trusted management of record entry instances is the objective of this document, continuously and consistently whether the instance is at rest or in motion, before/during/after each lifecycle event, across one or more systems.

Not many standards are available in this field and the ones relevant for health issues and medical equipment seem to be even fewer. For the purpose of GATEKEEPER project, there is also a gap in this field.

4.6.7 Data federation model

Federated Data Model (FDM) allows an organisation to extend data and business services to inquire data from multiple sources. FDM's goal is to make enterprise data available to all departments and partners of an organisation. Data federation is the creation of a virtual database that aggregates data from distributed sources giving them a common data model. It is an approach to data integration that provides a single source of data for front end applications. Federated analytics is an approach to user data analysis that does not capture data from individual devices. The idea has circled for a few years, but Google has introduced federated analytics to a wider audience. They define it as "Collaborative data science without data collection".

In the GATEKEEPER project, identification, compliance and potential contribution to standardisation is in focus. In addition, the following aspects will need to be studied during the project:

- European framework for Data Spaces in Health Care. To position GATEKEEPER within the European Health Data Space (EHDS) initiative, which was launched in 2020 and it is part of the Commission Work programme 2021.
- Reference architecture model selection: IDSA, other. This was initiated by Task 3.1. It. needs to go further positioning GATEKEEPER data federation architecture more clearly in the context of EHDS implementation.
- Legislation and regulations: national and European. How European policies are going to be implemented in member states? What regulations are now in place? What could be the barriers for effective implementation?
- Data model of federation. Which data is going to be federated? Which data sets will be produced by pilots and then federated?

4.6.8 Products and services

Once the products and services that the GATEKEEPER project will offer to the respective sides in each marketplace (e.g. to health care supply, to technology supply, to consumers, to technology designers, etc) have been defined, including transaction price etc, several areas could potentially be relevant to investigate further, such as:

- Platform (WOT)
- Technical description-technical documentation
- Functional description (sales)
- Commercialisation models: PaaS, licensing, freemium, etc.
- Maintenance and services
- AI applications

These might be the applications developed and evaluated in the pilots, including OCs apps:

- Catalogue of applications
- Technical and functional descriptions
- Target use cases
- GK services to customers in market spaces

These services are the ones provided to customers of the marketplace, in their respective spaces:

- Other products and services

4.7 New area: standards for Edge Computing

4.7.1 Introduction

Edge computing is a distributed computing paradigm. That means that it is a system whose components are located on different networked computers, which communicate and coordinate their actions by passing messages to one another from any system. The components interact with one another to achieve a common goal.

4.7.2 Overview of relevant standards

There are several standards available, many of them Technical reports (TR) rather than standards, that affect Edge Computing in general. The ones deemed relevant to the GATEKEEPER projects are:

Number	Title	Description
ISO/IEC TR 23188:2020	Information technology — Cloud computing — Edge computing landscape	This is about the concept of edge computing, its relationship to cloud computing and IoT, and the technologies that are key to the implementation of edge computing. The topics are the concept of edge computing systems; the architectural foundation of edge computing; edge computing terminology; software classifications in edge computing, e.g. firmware, services,

		applications; supporting technologies, e.g. containers, serverless computing, microservices; networking for edge systems, including virtual networks; data, e.g. data flow, data storage, data processing; management, of software, of data and of networks, resources, quality of service; virtual placement of software and data, and metadata; real time; and mobile edge computing as well as mobile devices.
ISO/IEC TR 30164:2020	Internet of things (IoT) — Edge Computing	Data management, Terminology, Telecommunication, Computer networks, Internet
ISO/IEC TR 23188:2020	Information technology - Cloud computing - Edge computing landscape	This standard examines the concept of edge computing, its relationship to cloud computing and IoT, and the technologies that are key to the implementation of edge computing. This document explores the following topics with respect to edge computing: • concept of edge computing systems; • architectural foundation of edge computing; • edge computing terminology; • software classifications in edge computing, e.g. firmware, services, applications; • supporting technologies, e.g. containers, serverless computing, microservices; • networking for edge systems, including virtual networks; • data, e.g. data flow, data storage, data processing; • management, of software, of data and of networks, resources, quality of service; • virtual placement of software and data, and metadata; • security and privacy; • real time; • mobile edge computing, mobile devices.

ISO/IEC TR 30164:2020	Internet of Things (IoT) - Edge computing	This document describes the common concepts, terminologies, characteristics, use cases and technologies (including data management, coordination, processing, network functionality, heterogeneous computing, security, hardware/software optimisation) of edge computing for IoT systems applications. This document is also meant to assist in the identification of potential areas for standardisation in edge computing for IoT.
ISO/IEC TR 23186:2018	Information technology — Cloud computing — Framework of trust for processing of multi-sourced data	This document describes a framework of trust for the processing of multi-sourced data that includes data use obligations and controls, data provenance, chain of custody, security and immutable proof of compliance as elements of the framework.
ISO/IEC TR 30166:2020	Internet of Things (IoT) — Industrial IoT	Information technology, Standardisation, World Wide Web, Industrial, Internet
ISO/IEC TR 24030:2021	Information technology — Artificial Intelligence (AI) — Use cases	This document provides a collection of representative use cases of AI applications in a variety of domains.
ISO/IEC 30141:2018	Internet of Things (IoT) — Reference Architecture	This document specifies a general IoT Reference Architecture in terms of defining system characteristics, a Conceptual Model, a Reference Model and architecture views for IoT.
ISO/IEC 30137-1:2019	Information technology — Use of biometrics in video surveillance systems — Part 1: System design and specification.	Standardisation of generic biometric technologies pertaining to human beings to support interoperability and data interchange among applications and systems. Generic human biometric standards include: common file frameworks; biometric application.
ISO/IEC 24643:2020	Architecture for a distributed real-time access system	Interfaces (data processing), Time, Open systems interconnection, Physical layer (OSI), Network layer (OSI), Architecture

This list is not exhaustive.
As will be seen from this overview, the documents are all recent, and are mostly system oriented.

5. Conclusion

This report provides an updated overview of relevant standards available for the use in the GATEKEEPER project.

The gap analysis will provide input for contributions to new or existing standardisation initiatives covered in T8.2. The deliverable will also feed into the work of the business cluster and D9.5.2.

Appendix A List of relevant standards supporting the EU Directives on medical devices

Directive 93/42/EEC concerning medical devices (Publication of titles and references of harmonised standards under Union harmonisation legislation) (Text with EEA relevance) (2017/C 389/03) lists the following standards as harmonised standards for medical devices drafted in support of Directive 93/42/EEC:

1. EN 285:2006+A2:2009 Sterilization - Steam sterilizers - Large sterilizers

2. EN 455-1:2000 Medical gloves for single use - Part 1: Requirements and testing for freedom from holes.

3. EN 455-2:2009+A2:2013 Medical gloves for single use - Part 2: Requirements and testing for physical properties.

4. EN 455-3:2006 Medical gloves for single use - Part 3: Requirements and testing for biological evaluation.

5. EN 455-4:2009 Medical gloves for single use - Part 4: Requirements and testing for shelf life determination.

6. EN 556-1:2001 Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices EN 556-1:2001/AC:2006

7. EN 556-2:2015 Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 2: Requirements for aseptically processed medical devices.

8. EN 794-3:1998+A2:2009 Lung ventilators - Part 3: Specific requirements for emergency and transport ventilators

9. EN 1041:2008 Information supplied by the manufacturer of medical devices

10. EN 1060-3:1997+A2:2009 Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems.

11. EN 1060-4:2004 Non-invasive sphygmomanometers - Part 4: Test procedures to determine the overall system accuracy of automated non-invasive phygmomanometers.

12. EN ISO 1135-4:2011 Transfusion equipment for medical use - Part 4: Transfusion sets for single use (ISO 1135-4:2010).

13. EN 1282-2:2005+A1:2009 Tracheostomy tubes - Part 2: Paediatric tubes (ISO 5366-3:2001, modified).

14. EN 1422:1997+A1:2009 Sterilizers for medical purposes - Ethylene oxide sterilizers - Requirements and test methods.

15. EN 1618:1997 Catheters other than intravascular catheters - Test methods for common properties

16. EN 1639:2009 Dentistry - Medical devices for dentistry - Instruments

17. EN 1640:2009 Dentistry - Medical devices for dentistry - Equipment

18. EN 1641:2009 Dentistry - Medical devices for dentistry - Materials

19. EN 1642:2011 Dentistry - Medical devices for dentistry - Dental implants

20. EN 1707:1996 Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment - Lock fittings

21. EN 1782:1998+A1:2009 Tracheal tubes and connectors

22. EN 1789:2007+A1:2010 Medical vehicles and their equipment - Road ambulances

23. EN 1820:2005+A1:2009 Anaesthetic reservoir bags (ISO 5362:2000, modified)

24. EN 1865-1:2010+A1:2015 Patient handling equipment used in road ambulances - Part 1: General stretcher systems and patient handling equipment

25. EN 1865-2:2010+A1:2015 Patient handling equipment used in road ambulances - Part 2: Power assisted stretcher.

26. EN 1865-3:2012 Patient handling equipment used in road ambulances - Part 3: Heavy duty stretcher

27. EN 1865-4:2012 Patient handling equipment used in road ambulances - Part 4: Foldable patient transfer chair.

28. EN 1865-5:2012 Patient handling equipment used in road ambulances - Part 5: Stretcher support.

29. EN 1985:1998 Walking aids - General requirements and test methods Notice: This standard still needs to be amended to take into account the requirements introduced by Directive 2007/47/EC. The amended standard will be published by CEN as soon as possible. Manufacturers are advised to check whether all relevant essential requirements of the amended directive are appropriately covered.

30. EN ISO 3826-2:2008 Plastics collapsible containers for human blood and blood components - Part 2: Graphical symbols for use on labels and instruction leaflets (ISO 3826-2:2008).

31. EN ISO 3826-3:2007 Plastics collapsible containers for human blood and blood components - Part 3: Blood bag systems with integrated features (ISO 3826- 3:2006).

32. EN ISO 3826-4:2015 Plastics collapsible containers for human blood and blood components - Part 4: Aphaeresis blood bag systems with integrated features (ISO 3826-4:2015).

33. EN ISO 4074:2002 Natural latex rubber condoms - Requirements and test methods (ISO 4074:2002).

34. EN ISO 4135:2001Anaesthetic and respiratory equipment - Vocabulary (ISO 4135:2001)..

35. EN ISO 5359:2008 Low-pressure hose assemblies for use with medical gases (ISO 5359:2008)

EN ISO 5359:2008/A1:2011

36. EN ISO 5360:2009 Anaesthetic vaporizers - Agent-specific filling systems (ISO 5360:2006).

37. EN ISO 5366-1:2009 Anaesthetic and respiratory equipment - Tracheostomy tubes - Part 1: Tubes and connectors for use in adults (ISO 5366-1:2000).

38. EN ISO 5840:2009 Cardiovascular implants - Cardiac valve prostheses (ISO 5840:2005).

39. EN ISO 7197:2009 Neurosurgical implants - Sterile, single-use hydrocephalus shunts and components (ISO 7197:2006, including Cor 1:2007).

40. EN ISO 7376:2009 Anaesthetic and respiratory equipment - Laryngoscopes for tracheal intubation (ISO 7376:2009).

41. EN ISO 7396-1:2007 Medical gas pipeline systems - Part 1: Pipeline systems for compressed medical gases and vacuum (ISO 7396-1:2007)

EN ISO 7396-1:2007/A1:2010

EN ISO 7396-1:2007/A2:2010.

42. EN ISO 7396-2:2007 Medical gas pipeline systems - Part 2: Anaesthetic gas scavenging disposal systems (ISO 7396-2:2007).

43. EN ISO 7886-3:2009 Sterile hypodermic syringes for single use - Part 3: Auto-disable syringes for fixed-dose immunization (ISO 7886-3:2005).

44. EN ISO 7886-4:2009 Sterile hypodermic syringes for single use - Part 4: Syringes with reuse prevention feature (ISO 7886-4:2006).

45. EN ISO 8185:2009 Respiratory tract humidifiers for medical use – Specific requirements for respiratory humidification systems (ISO8185:2007).

46. EN ISO 8359:2009 oxygen concentrators for medical use - Safety requirements (ISO 8359:1996)

EN ISO 8359:2009/A1:2012.

47. EN ISO 8835-2:2009 Inhalational anaesthesia systems - Part 2: Anaesthetic breathing systems (ISO 8835- 2:2007).

48. EN ISO 8835-3:2009 Inhalational anaesthesia systems - Part 3: Transfer and receiving systems of active anaesthetic gas scavenging systems (ISO 8835-3:2007)

EN ISO 8835-3:2009/A1:2010.

49. EN ISO 8835-4:2009 Inhalational anaesthesia systems - Part 4: Anaesthetic vapour delivery devices (ISO 8835- 4:2004).

50. EN ISO 8835-5:2009 Inhalational anaesthesia systems - Part 5: Anaesthetic ventilators (ISO 8835-5:2004).

51. EN ISO 9170-1:2008 Terminal units for medical gas pipeline systems - Part 1: Terminal units for use with compressed medical gases and vacuum (ISO 9170-1:2008).

52. EN ISO 9170-2:2008 Terminal units for medical gas pipeline systems - Part 2: Terminal units for anaesthetic gas scavenging systems (ISO 9170-2:2008).

53. EN ISO 9360-1:2009 Anaesthetic and respiratory equipment - Heat and moisture exchangers (HMEs) for humidifying respired gases in humans - Part 1: HMEs for use with minimum tidal volumes of 250 ml (ISO 9360-1:2000).

54. EN ISO 9360-2:2009 Anaesthetic and respiratory equipment - Heat and moisture exchangers (HMEs) for humidifying respired gases in humans - Part 2: HMEs for use with tracheostomized patients having minimum tidal volumes of 250 ml (ISO 9360-2:2001).

55. EN ISO 9713:2009 Neurosurgical implants - Self-closing intracranial aneurysm clips (ISO 9713:2002).

56. EN ISO 10079-1:2009 Medical suction equipment - Part 1: Electrically powered suction equipment - Safety requirements (ISO 10079-1:1999).

57. EN ISO 10079-2:2009 Medical suction equipment - Part 2: Manually powered suction equipment (ISO 10079-2:1999).

58. EN ISO 10079-3:2009 Medical suction equipment - Part 3: Suction equipment powered from a vacuum or pressure source (ISO 10079-3:1999).

59. EN ISO 10328:2016 Prosthetics - Structural testing of lower-limb prostheses - Requirements and test methods (ISO 10328:2016).

60. EN ISO 10524-1:2006 Pressure regulators for use with medical gases - Part 1: Pressure regulators and pressure regulators with flowmetering devices (ISO 10524-1:2006).

61. EN ISO 10524-2:2006 Pressure regulators for use with medical gases - Part 2: Manifold and line pressure regulators (ISO 10524-2:2005).

62. EN ISO 10524-3:2006 Pressure regulators for use with medical gases - Part 3: Pressure regulators integrated with cylinder valves (ISO 10524-3:2005).

63. EN ISO 10524-4:2008 Pressure regulators for use with medical gases - Part 4: Low-pressure regulators (ISO 10524- 4:2008).

64. EN ISO 10535:2006 hoists for the transfer of disabled persons - Requirements and test methods (ISO 10535:2006).

Notice: This standard still needs to be amended to take into account the requirements introduced by Directive 2007/47/EC. The amended standard will be published by CEN as soon as possible. Manufacturers are advised to check whether all relevant essential requirements of the amended directive are appropriately covered.

65. EN ISO 10555-1:2009 Sterile, single-use intravascular catheters - Part 1: General requirements (ISO 10555-1:1995, including Amd 1:1999 and Amd 2:2004).

66. EN ISO 10651-2:2009 Lung ventilators for medical use - Particular requirements for basic safety and essential performance - Part 2: Home care ventilators for ventilator-dependent patients (ISO 10651- 2:2004).

67. EN ISO 10651-4:2009 Lung ventilators - Part 4: Specific requirements for operator-powered resuscitators (ISO 10651-4:2002).

68. EN ISO 10651-6:2009 Lung ventilators for medical use - Particular requirements for basic safety and essential performance - Part 6: Home-care ventilatory support devices (ISO 10651-6:2004).

69. EN ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)

EN ISO 10993-1:2009/AC:2010.

70. EN ISO 10993-3:2014 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2014).

71. EN ISO 10993-4:2009 Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood (ISO 10993-4:2002, including Amd 1:2006).

72. EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009).

73. EN ISO 10993-6:2009 Biological evaluation of medical devices - Part 6: Tests for local effects after implantation (ISO 10993-6:2007).

74. EN ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (ISO 10993-7:2008).

EN ISO 10993-7:2008/AC:2009

75. EN ISO 10993-9:2009 Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products (ISO 10993-9:2009).

76. EN ISO 10993-11:2018 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017).

77. EN ISO 10993-12:2012 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2012).

78. EN ISO 10993-13:2010 Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices (ISO 10993-13:2010).

79. EN ISO 10993-14:2009 Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products from ceramics (ISO 10993-14:2001).

80. EN ISO 10993-15:2009 Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys (ISO 10993-15:2000).

81. EN ISO 10993-16:2010 Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables (ISO 10993-16:2010).

82. EN ISO 10993-17:2009 Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances (ISO 10993-17:2002).

83. EN ISO 10993-18:2009 Biological evaluation of medical devices - Part 18: Chemical characterization of materials (ISO 10993-18:2005).

84. EN ISO 11135-1:2007 Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11135-1:2007).

85. EN ISO 11137-1:2015 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006, including Amd 1:2013)

EN ISO 11137-1:2015/A2:2019.

86. EN ISO 11137-2:2015 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:2013).

87. EN ISO 11138-2:2009 Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138-2:2006).

88. EN ISO 11138-3:2009 Sterilization of health care products - Biological indicators - Part 3: Biological indicators for moist heat sterilization processes (ISO 11138-3:2006).

89. EN ISO 11140-1:2009 Sterilization of health care products - Chemical indicators - Part 1: General requirements (ISO 11140-1:2005).

90. EN ISO 11140-3:2009 Sterilization of health care products - Chemical indicators - Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test (ISO 11140-3:2007, including Cor 1:2007).

91. EN ISO 11197:2009 Medical supply units (ISO 11197:2004).

92. EN ISO 11607-1:2009 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006).

93. EN ISO 11607-2:2006 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2006).

94. EN ISO 11608-7:2017 Needle-based injection systems for medical use - Requirements and test methods - Part 7: Accessibility for persons with visual impairment (ISO 11608-7:2016).

95. EN ISO 11737-1:2006 Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2006).

EN ISO 11737-1:2006/AC:2009

96. EN ISO 11737-2:2009 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2009).

97. EN ISO 11810-1:2009 Lasers and laser-related equipment - Test method and classification for the laser resistance of surgical drapes and/or patient protective covers - Part 1: Primary ignition and penetration (ISO 11810-1:2005).

98. EN ISO 11810-2:2009 Lasers and laser-related equipment - Test method and classification for the laser-resistance of surgical drapes and/or patient-protective covers - Part 2: Secondary ignition (ISO 11810-2:2007).

99. EN ISO 11979-8:2009 Ophthalmic implants - Intraocular lenses - Part 8: Fundamental requirements (ISO 11979- 8:2006).

100. EN ISO 11990:2018 Lasers and laser-related equipment - Determination of laser resistance of tracheal tube shaft and tracheal cuffs (ISO 11990:2018).

101. EN 12006-2:1998+A1:2009 Non active surgical implants - Particular requirements for cardiac and vascular implants - Part 2: Vascular prostheses including cardiac valve conduits.

102. EN 12006-3:1998+A1:2009 Non active surgical implants - Particular requirements for cardiac and vascular implants - Part 3: Endovascular devices.

103. EN 12183:2009 Manual wheelchairs - Requirements and test methods.

104. EN 12184:2009 Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods.

105. EN 12342:1998+A1:2009 Breathing tubes intended for use with anaesthetic apparatus and ventilators.

106. EN 12470-1:2000+A1:2009 Clinical thermometers - Part 1: Metallic liquid- in-glass thermometers with maximum device.

107. EN 12470-2:2000+A1:2009 Clinical thermometers - Part 2: Phase change type (dot matrix) thermometers.

108. EN 12470-3:2000+A1:2009 Clinical thermometers - Part 3: Performance of compact electrical thermometers (non-predictive and predictive) with maximum device.

109. EN 12470-4:2000+A1:2009 Clinical thermometers - Part 4: Performance of electrical thermometers for continuous measurement.

110. EN 12470-5:2003 Clinical thermometers - Part 5: Performance of infra-red ear thermometers (with maximum device) Notice: This standard still needs to be amended to take into account the requirements introduced by Directive 2007/47/EC. The amended standard will be published by CEN as soon as possible. Manufacturers are advised to check whether all relevant essential requirements of the amended directive are appropriately covered.

111. EN ISO 12870:2009 Ophthalmic optics - Spectacle frames - Requirements and test methods (ISO 12870:2004).

112. EN 13060:2014 Small steam sterilizers.

113. EN ISO 13408-1:2015 Aseptic processing of health care products - Part 1: General requirements (ISO 13408-1:2008, including Amd 1:2013).

114. EN ISO 13408-2:2018 Aseptic processing of health care products - Part 2: Sterilizing filtration (ISO 13408-2:2018).

115. EN ISO 13408-3:2011 Aseptic processing of health care products - Part 3: Lyophilization (ISO 13408-3:2006).

116. EN ISO 13408-4:2011 Aseptic processing of health care products - Part 4: Clean-in-place technologies (ISO 13408-4:2005).

117. EN ISO 13408-5:2011 Aseptic processing of health care products - Part 5: Sterilization in place (ISO 13408-5:2006).

118. EN ISO 13408-6:2011 Aseptic processing of health care products - Part 6: Isolator systems (ISO 13408-6:2005).

119. EN ISO 13408-7:2015 Aseptic processing of health care products - Part 7: Alternative processes for medical devices and combination products (ISO 13408-7:2012).

120. EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016).

EN ISO 13485:2016/AC:2018

121. EN 13544-1:2007+A1:2009 Respiratory therapy equipment - Part 1: Nebulizing systems and their component.

122. EN 13544-2:2002+A1:2009 Respiratory therapy equipment - Part 2: Tubing and connectors.

123. EN 13544-3:2001+A1:2009 Respiratory therapy equipment - Part 3: Air entrainment devices.

124. EN 13624:2003 Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants for instruments used in the medical area - Test method and requirements (phase 2, step 1).

125. EN 13718-1:2008 Medical vehicles and their equipment - Air ambulances - Part 1: Requirements for medical devices used in air ambulances.

126. EN 13718-2:2015 Medical vehicles and their equipment - Air ambulances - Part 2: Operational and technical requirements for air ambulances.

127. EN 13726-1:2002 Test methods for primary wound dressings - Part 1: Aspects of absorbency

EN 13726-1:2002/AC:2003.

128. EN 13726-2:2002 Test methods for primary wound dressings - Part 2: Moisture vapour transmission rate of permeable film dressings.

129. EN 13727:2012 Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity in the medical area - Test method and requirements (phase 2, step 1).

130. EN 13795-1:2019 Surgical clothing and drapes - Requirements and test methods - Part 1: Surgical drapes and gowns.

131. EN 13795-2:2019 Surgical clothing and drapes - Requirements and test methods - Part 2: Clean air suits.

132. EN 13867:2002+A1:2009 Concentrates for haemodialysis and related therapies.

133. EN 13976-1:2011 Rescue systems - Transportation of incubators - Part 1: Interface conditions.

134. EN 13976-2:2018 Rescue systems - Transportation of incubators - Part 2: System requirements.

135. EN 14079:2003 Non-active medical devices - Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze.

136. EN 14139:2010 Ophthalmic optics - Specifications for ready-to- wear spectacles.

137. EN ISO 14155:2011 Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2011)

EN ISO 14155:2011/AC:2011.

138. EN 14180:2003+A2:2009 Sterilizers for medical purposes - Low temperature steam and formaldehyde sterilizers - Requirements and testing.

139. EN 14348:2005 Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants - Test methods and requirements (phase 2, step 1).

140. EN ISO 14408:2009 Tracheal tubes designed for laser surgery - Requirements for marking and accompanying information (ISO 14408:2005).

141. EN 14561:2006 Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area - Test method and requirements (phase 2, step 2).

142. EN 14562:2006 Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of fungicidal or yeasticidal activity for instruments used in the medical area - Test method and requirements (phase 2, step 2).

143. EN 14563:2008 Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of mycobactericidal or tuberculocidal activity of chemical disinfectants used for instruments in the medical area - Test method and requirements (phase 2, step 2).

144. EN ISO 14602:2011 Non-active surgical implants - Implants for osteosynthesis - Particular requirements (ISO 14602:2010).

145. EN ISO 14607:2009 Non-active surgical implants - Mammary implants - Particular requirements (ISO 14607:2007).

146. EN ISO 14630:2009 Non-active surgical implants - General requirements (ISO 14630:2008).

147. EN 14683:2019+AC:2019 Medical face masks - Requirements and test methods.

148. EN ISO 14889:2009 Ophthalmic optics - Spectacle lenses - Fundamental requirements for uncut finished lenses (ISO 14889:2003).

149. EN 14931:2006 Pressure vessels for human occupancy (PVHO) - Multi-place pressure chamber systems for hyperbaric therapy - Performance, safety requirements and testing.

150. EN ISO 14937:2009 Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices (ISO 14937:2009).

151. EN ISO 14971:2012 Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007- 10-01).

152. EN ISO 15001:2011 Anaesthetic and respiratory equipment - Compatibility with oxygen (ISO 15001:2010).

153. EN ISO 15002:2008 Flow-metering devices for connection to terminal units of medical gas pipeline systems (ISO 15002:2008).

154. EN ISO 15004-1:2009 Ophthalmic instruments - Fundamental requirements and test methods - Part 1: General requirements applicable to all ophthalmic instruments (ISO 15004-1:2006).

155. EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03).

156. EN ISO 15747:2019 Plastic containers for intravenous injections (ISO 15747:2018).

157. EN ISO 15798:2010 Ophthalmic implants - Ophthalmic viscosurgical devices (ISO 15798:2010).

158. EN ISO 15883-1:2009 Washer-disinfectors - Part 1: General requirements, terms and definitions and tests (ISO 15883-1:2006).

159. EN ISO 15883-2:2009 Washer-disinfectors - Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc. (ISO 15883-2:2006).

160. EN ISO 15883-3:2009 Washer-disinfectors - Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers (ISO 15883-3:2006).

161. EN ISO 15883-4:2018 Washer-disinfectors - Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes (ISO 15883-4:2018).

162. EN 15986:2011 Symbol for use in the labelling of medical devices - Requirements for labelling of medical devices containing phthalate.

163. EN ISO 16061:2009 Instrumentation for use in association with non- active surgical implants - General requirements (ISO 16061:2008, Corrected version 2009-03- 15).

164. EN ISO 16201:2006 Technical aids for disabled persons - Environmental control systems for daily living (ISO 16201:2006).

165. EN ISO 17510-1:2009 Sleep apnoea breathing therapy - Part 1: Sleep apnoea breathing therapy equipment (ISO 17510-1:2007).

166. EN ISO 17510-2:2009 Sleep apnoea breathing therapy - Part 2: Masks and application accessories (ISO 17510-2:2007).

167. EN ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices (ISO 17664:2017).

168. EN ISO 17665-1:2006 Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665-1:2006).

169. EN ISO 18777:2009 Transportable liquid oxygen systems for medical use - Particular requirements (ISO 18777:2005).

170. EN ISO 18778:2009 Respiratory equipment - Infant monitors - Particular requirements (ISO 18778:2005).

171. EN ISO 18779:2005 Medical devices for conserving oxygen and oxygen mixtures - Particular requirements (ISO 18779:2005).

172. EN ISO 19054:2006 Rail systems for supporting medical equipment (ISO 19054:2005).

173. EN 20594-1:1993 Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements (ISO 594-1:1986).

EN 20594-1:1993/A1:1997

EN 20594-1:1993/AC:1996

174. EN ISO 21534:2009 Non-active surgical implants - Joint replacement implants - Particular requirements (ISO 21534:2007)..

175. EN ISO 21535:2009 Non-active surgical implants - Joint replacement implants - Specific requirements for hip- joint replacement implants (ISO 21535:2007)

176. EN ISO 21536:2009 Non-active surgical implants - Joint replacement implants - Specific requirements for knee- joint replacement implants (ISO 21536:2007).

177. EN ISO 21649:2009 Needle-free injectors for medical use - Requirements and test methods (ISO 21649:2006).

178. EN ISO 21969:2009 High-pressure flexible connections for use with medical gas systems (ISO 21969:2009).

179. EN ISO 21987:2017 Ophthalmic optics - Mounted spectacle lenses (ISO 21987:2017).

180. EN ISO 22442-1:2007 Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk management (ISO 22442-1:2007).

181. EN ISO 22442-2:2007 Medical devices utilizing animal tissues and their derivatives - Part 2: Controls on sourcing, collection and handling (ISO 22442-2:2007).

182. EN ISO 22442-3:2007 Medical devices utilizing animal tissues and their derivatives - Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents (ISO 22442-3:2007).

183. EN ISO 22523:2006 External limb prostheses and external orthoses - Requirements and test methods (ISO 22523:2006).

Notice: This standard still needs to be amended to take into account the requirements introduced by Directive 2007/47/EC. The amended standard will be published by CEN as soon as possible. Manufacturers are advised to check whether all relevant essential requirements of the amended directive are appropriately covered.

184. EN ISO 22675:2016 Prosthetics - Testing of ankle-foot devices and foot units - Requirements and test methods (ISO 22675:2016).

185. EN ISO 23328-1:2008 Breathing system filters for anaesthetic and respiratory use - Part 1: Salt test method to assess filtration performance (ISO 23328- 1:2003).

186. EN ISO 23328-2:2009 Breathing system filters for anaesthetic and respiratory use - Part 2: Non-filtration aspects (ISO 23328-2:2002)..

187. EN ISO 23747:2009 Anaesthetic and respiratory equipment - Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans (ISO 23747:2007).

188. EN ISO 25424:2019 Sterilization of health care products - Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 25424:2018).

189. EN ISO 25539-1:2009 Cardiovascular implants - Endovascular devices - Part 1: Endovascular prostheses (ISO 25539-1:2003 including Amd 1:2005)

EN ISO 25539-1:2009/AC:2011.

190. EN ISO 25539-2:2009 Cardiovascular implants - Endovascular devices - Part 2: Vascular stents (ISO 25539- 2:2008) EN ISO 25539-2:2009/AC:2011.

191. EN ISO 26782:2009 Anaesthetic and respiratory equipment - Spirometers intended for the measurement of time forced expired volumes in humans (ISO 26782:2009).

EN ISO 26782:2009/AC:2009.

192. EN 27740:1992 Instruments for surgery, scalpels with detachable blades, fitting dimensions (ISO 7740:1985).

EN 27740:1992/A1:1997.

EN 27740:1992/AC:1996.

193. EN 60118-13:2005 Electroacoustics - Hearing aids - Part 13: Electromagnetic compatibility (EMC) (IEC 60118-13:2004)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

194. EN 60522:1999 Determination of the permanent filtration of X- ray tube assemblies (IEC 60522:1999)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

195. EN 60580:2000 Medical electrical equipment - Dose area product meters (IEC 60580:2000)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

196. EN 60601-1:2006 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005)

EN 60601-1:2006/AC:2010

EN 60601-1:2006/A1:2013 (IEC 60601-1:2005/A1:2012)

197. EN 60601-1-1:2001 Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems (IEC 60601-1-1:2000) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

198. EN 60601-1-2:2015 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance -

Collateral Standard: Electromagnetic disturbances - Requirements and tests (IEC 60601-1-2:2014)

199. EN 60601-1-3:2008 Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment (IEC 60601-1-3:2008)

EN 60601-1-3:2008/AC:2010

EN 60601-1-3:2008/A11:2016.

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

200. EN 60601-1-4:1996 Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems (IEC 60601-1-4:1996)

EN 60601-1-4:1996/A1:1999 (IEC 60601-1-4:1996/A1:1999)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

201. EN 60601-1-6:2010 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability (IEC 60601-1-6:2010). Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

202. EN 60601-1-8:2007 Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems (IEC 60601-1-8:2006)

EN 60601-1-8:2007/AC:2010

EN 60601-1-8:2007/A11:2017.

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

203. EN 60601-1-10:2008 Medical electrical equipment - Part 1-10: General requirements for basic safety and essential performance - Collateral Standard: Requirements for the development of physiologic closed-loop controllers (IEC 60601- 1-10:2007) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

204. EN 60601-1-11:2010 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for

medical electrical equipment and medical electrical systems used in the home healthcare environment (IEC 60601-1-11:2010)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

205. EN 60601-2-1:1998 Medical electrical equipment - Part 2-1: Particular requirements for the safety of electron accelerators in the range of 1 MeV to 50 MeV (IEC 60601-2-1:1998) EN 60601-2-1:1998/A1:2002 (IEC 60601-2-1:1998/A1:2002)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

206. EN 60601-2-2:2009 Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories (IEC 60601-2-2:2009)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

207. EN 60601-2-3:1993 Medical electrical equipment - Part 2: Particular requirements for the safety of short-wave therapy equipment (IEC 60601-2-3:1991)

EN 60601-2-3:1993/A1:1998 (IEC 60601-2-3:1991/A1:1998)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

208. EN 60601-2-4:2003 Medical electrical equipment - Part 2-4: Particular requirements for the safety of cardiac defibrillators (IEC 60601- 2-4:2002)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

209. EN 60601-2-5:2000 Medical electrical equipment - Part 2-5: Particular requirements for the safety of ultrasonic physiotherapy equipment (IEC 60601-2-5:2000)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

210. EN 60601-2-8:1997 Medical electrical equipment - Part 2: Particular requirements for the safety of therapeutic X-ray equipment operating in the range 10 kV to 1 MV (IEC 60601-2-8:1987)

EN 60601-2-8:1997/A1:1997 (IEC 60601-2-8:1987/A1:1997)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

211. EN 60601-2-10:2000 Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators (IEC 60601-2-10:1987)

EN 60601-2-10:2000/A1:2001 (IEC 60601-2-10:1987/A1:2001)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

212. EN 60601-2-11:1997 Medical electrical equipment - Part 2-11: Particular requirements for the safety of gamma beam therapy equipment (IEC 60601-2-11:1997)

EN 60601-2-11:1997/A1:2004 (IEC 60601-2-11:1997/A1:2004)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

213. EN 60601-2-12:2006 Medical electrical equipment - Part 2-12: Particular requirements for the safety of lung ventilators - Critical care ventilators (IEC 60601-2-12:2001).

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

214. EN 60601-2-13:2006 Medical electrical equipment - Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems (IEC 60601-2-13:2003)

EN 60601-2-13:2006/A1:2007 (IEC 60601-2-13:2003/A1:2006)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

215. EN 60601-2-16:1998 Medical electrical equipment - Part 2-16: Particular requirements for the safety of haemodialysis, haemodiafiltration and haemofiltration equipment (IEC 60601-2-16:1998)

EN 60601-2-16:1998/AC:1999

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

216. EN 60601-2-17:2004 Medical electrical equipment - Part 2-17: Particular requirements for the safety of automatically-controlled brachytherapy afterloading equipment (IEC 60601-2-17:2004)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

217. EN 60601-2-18:1996 Medical electrical equipment - Part 2-18: Particular requirements for the safety of endoscopic equipment (IEC 60601-2-18:1996)

EN 60601-2-18:1996/A1:2000 (IEC 60601-2-18:1996/A1:2000)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

218. EN 60601-2-19:2009 Medical electrical equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators (IEC 60601-2-19:2009)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

219. EN 60601-2-20:2009 Medical electrical equipment - Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators (IEC 60601-2-20:2009)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

220. EN 60601-2-21:2009 Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers (IEC 60601-2-21:2009)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

221. EN 60601-2-22:1996 Medical electrical equipment - Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment (IEC 60601-2-22:1995)

Notice: This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

222. EN 60601-2-23:2000 Medical electrical equipment - Part 2-23: Particular requirements for the safety, including essential performance, of transcutaneous partial pressure monitoring equipment (IEC 60601-2-23:1999)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

223. EN 60601-2-24:1998 Medical electrical equipment - Part 2-24: Particular requirements for the safety of infusion pumps and controllers (IEC 60601-2-24:1998)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

224. EN 60601-2-25:1995 Medical electrical equipment - Part 2-25: Particular requirements for the safety of electrocardiographs (IEC 60601-2-25:1993)

EN 60601-2-25:1995/A1:1999 (IEC 60601-2-25:1993/A1:1999)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

225. EN 60601-2-26:2003 Medical electrical equipment - Part 2-26: Particular requirements for the safety of electroencephalographs (IEC 60601-2-26:2002)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

226. EN 60601-2-27:2006 Medical electrical equipment - Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment (IEC 60601-2-27:2005)

EN 60601-2-27:2006/AC:2006

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

227. EN 60601-2-28:2010 Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis (IEC 60601-2-28:2010)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

228. EN 60601-2-29:2008 Medical electrical equipment - Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators (IEC 60601-2-29:2008)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

229. EN 60601-2-30:2000 Medical electrical equipment - Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment (IEC 60601-2-30:1999)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

230. EN 60601-2-33:2010 Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis (IEC 60601-2-33:2010)

EN 60601-2-33:2010/A1:2015 (IEC 60601-2-33:2010/A1:2013)

EN 60601-2-33:2010/A2:2015 (IEC 60601-2-33:2010/A2:2015)

EN 60601-2-33:2010/AC:2016-03

EN 60601-2-33:2010/A12:2016

231. EN 60601-2-34:2000 Medical electrical equipment - Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment (IEC 60601-2-34:2000) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

232. EN 60601-2-36:1997 Medical electrical equipment - Part 2: Particular requirements for the safety of equipment for extracorporeally induced lithotripsy (IEC 60601-2-36:1997)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

233. EN 60601-2-37:2008 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment (IEC 60601-2-37:2007)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

234. EN 60601-2-39:2008 Medical electrical equipment - Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment (IEC 60601-2-39:2007)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

235. EN 60601-2-40:1998 Medical electrical equipment - Part 2-40: Particular requirements for the safety of electromyographs and evoked response equipment (IEC 60601-2-40:1998)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

236. EN 60601-2-41:2009 Medical electrical equipment - Part 2-41: Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for diagnosis (IEC 60601-2-41:2009)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

237. EN 60601-2-43:2010 Medical electrical equipment - Part 2-43: Particular requirements for basic safety and essential performance of Xray equipment for interventional procedures (IEC 60601-2-43:2010)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

238. EN 60601-2-44:2009 Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography (IEC 60601-2-44:2009)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

239. EN 60601-2-45:2001 Medical electrical equipment - Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices (IEC 60601-2-45:2001)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

240. EN 60601-2-46:1998 Medical electrical equipment - Part 2-46: Particular requirements for the safety of operating tables (IEC 60601-2-46:1998)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

241. EN 60601-2-47:2001 Medical electrical equipment - Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems (IEC 60601-2-47:2001)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

242. EN 60601-2-49:2001 Medical electrical equipment - Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment (IEC 60601-2-49:2001)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

243. EN 60601-2-50:2009 Medical electrical equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment (IEC 60601-2-50:2009)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

244. EN 60601-2-51:2003 Medical electrical equipment - Part 2-51: Particular requirements for safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs (IEC 60601-2-51:2003)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

245. EN 60601-2-52:2010 Medical electrical equipment - Part 2-52: Particular requirements for basic safety and essential performance of medical beds (IEC 60601-2-52:2009)

EN 60601-2-52:2010/AC:2011

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

246. EN 60601-2-54:2009 Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy (IEC 60601-2-54:2009)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

247. EN 60627:2001 Diagnostic X-ray imaging equipment - Characteristics of general purpose and mammographic anti-scatter grids (IEC 60627:2001)

EN 60627:2001/AC:2002

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

248. EN 60645-1:2001 Electroacoustics - Audiological equipment - Part 1: Pure-tone audiometers (IEC 60645-1:2001)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

249. EN 60645-2:1997 Audiometers - Part 2: Equipment for speech audiometry (IEC 60645-2:1993)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

250. EN 60645-3:2007 Electroacoustics - Audiometric equipment - Part 3: Test signals of short duration (IEC 60645-3:2007)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

251. EN 60645-4:1995 Audiometers - Part 4: Equipment for extended high-frequency audiometry (IEC 60645-4:1994)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

252. EN 61217:2012 Radiotherapy equipment - Coordinates, movements and scales (IEC 61217:2011)

253. EN 61676:2002 Medical electrical equipment - Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology (IEC 61676:2002)

EN 61676:2002/A1:2009 (IEC 61676:2002/A1:2008)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

254. EN 62083:2009 Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems (IEC 62083:2009)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

255. EN 62220-1:2004 Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1: Determination of the detective quantum efficiency (IEC 62220-1:2003)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

256. EN 62220-1-2:2007 Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-2: Determination of the detective quantum efficiency - Detectors used in mammography (IEC 62220-1-2:2007)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

257. EN 62220-1-3:2008 Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-3: Determination of the detective quantum efficiency - Detectors used in dynamic imaging (IEC 62220-1-3:2008)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

258. EN 62304:2006 Medical device software - Software life-cycle processes (IEC 62304:2006)

EN 62304:2006/AC:2008

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

259. EN 62366:2008 Medical devices - Application of usability engineering to medical devices (IEC 62366:2007)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

260. EN 80601-2-35:2009 Medical electrical equipment - Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use (IEC 80601- 2-35:2009)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

261. EN 80601-2-58:2009 Medical electrical equipment - Part 2-58: Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery (IEC 80601-2-58:2008)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

262. EN 80601-2-59:2009 Medical electrical equipment - Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening (IEC 80601-2-59:2008)

Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

263. EN ISO 81060-1:2012 Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type (ISO 81060-1:2007).

264. EN ISO 81060-2:2019 Non-invasive sphygmomanometers - Part 2: Clinical investigation of intermittent automated measurement type (ISO 81060-2:2018).