PHOTONICS21

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Report on the standardization landscape and applicable standards

The objetvie of this document is to compile the existing standards and on-going projects that are relevant for the MIRACLE project, and the relevant standardization technical committees.

Project Documentation Sheet	
Project	Mid-infrared arthroscopy innovative imaging system for real-time clinical in depth examination and diagnosis of degenerative joint diseases
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Coordinator	Gabriela Lorite (UOULU)
Consortium partners	University of Oulu (Finland) – UOULU Ulm University (Germany) – UULM University of Eastern Finland (Finland) – UEF Norwegian University of Life Sciences (Norway) – NMBU Kuopio University Hospital (Finland) – KUH Utrecht University (The Netherlands) – UU Nanoplus (Germany) – NP OptoPrecision (Germany) – OP Innovacio I Recerca Industrial I Sostenible SL (Spain) – IRIS Art Photonics (Germany) – AP Instituto Nacional de Engenharia Biomedica (Portugal) – INEB Asociación Española de Normalización (Spain) – UNE Photonics Finland (Finland) – PF

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Contents

1. List of Abbreviations

This page is provided as a reference source to help the reader in the event that those terms or abbreviations are encountered are unfamiliar, or are used in a specific sense in the document.

The following abbreviations related to standardization are used:

1.1. Standardization Organizations

UNE	Spanish Association for Standardization
CEN	European Committee for Standardization
CENELEC (CLC)	European Committee for Standardization in the Electrical field
ISO	International Organization for Standardization
IEC	International Electrotechnical Commission
TC	Technical Committee
SC	Subcommiteee
WG	Working Group

1.2. Standardization Documents

EN	European Standard
TR	Technical Report
TS	Technical Specification
HD	Harmonization Document
CWA	CEN Workshop Agreement
ISO	International Standard
IEC	International Standard
IWA	International Workshop Agreement
PAS	Public Available Specification (ISO)
WI	Work Item
prEN	Project of European Standard
FprEN	Final Project of European Standard
WD	Working Draft
CD	International Committee Draft
CDV	Committee Draft for Voting (IEC)
DIS	Draft International Standard
FDIS	Final Draft International Standard

2. Executive Summary

UNE, the Spanish Association for Standardization and Certification, as an European Standardization Body, is providing support regarding the standardization tasks included in the project. This document is providing answer to Task 7.5 Standardization activities, and in particular is the result of SubTask T7.5.1, Analysis of the applicable standardization landscape. In order to fulfil this commitment, this deliverable D7.16 'Report on the standardization landscape and applicable standards' has been prepared to provide the partners with information about the relevant state-of-the-art in standardization, including related standardization technical committees, published standards and standards under development, which can be of interest for the project objectives and development.

The objectives of D7.16 are:

- to facilitate the acceptance and utilization by the market of the developed solution proposed by the MIRACLE project,

- to ensure compatibility and interoperability with what already exists in the market, and

- to identify the relevant standardization technical committees with potential interest in order to complement the dissemination plan of the MIRACLE project.

3. Introduction

Standards are voluntary technical documents that set out requirements for a specific item, material, component, system or service, or describes in detail a particular method, procedure or best practice. Standards are developed and defined through a process of sharing knowledge and building consensus among technical experts nominated by interested parties and other stakeholders - including businesses, consumers and environmental groups, among others. These experts are organized in Technical Committees (TCs), which are subdivided in Subcommittees (SCs) and/or Working Groups (WGs). These TCs are included in the structure of the Standardization Organizations (National, European and International, with the respective mirror committees) and work following their internal regulations.

The standardization bodies operate at National (UNE, AFNOR, BSI, DIN, etc.), Regional (CEN, CENELEC, ETSI) or International (ISO, IEC) level. Sometimes there are different standardization bodies at the same level, but covering different fields. This is the case of ISO (general) and IEC (electrical) at International level, or CEN, CENELEC and ETSI at European level in the same way.

In the next subclauses, more detailed information is provided.

3.1 National Standardization Organizations

The National Standardization Organizations (UNE, AFNOR, BSI, DIN, etc.) are the organizations officially recognized at national level as being able to represent all standardization interests in their country. They are responsible for developing national standards in their countries and they are the members of ISO, IEC, CEN and CENELEC (note that ITU and ETSI have a different membership policy). National stakeholders interested in standardization activities are able to take part in the process at European or International level through their national standardization organization.

The legal status of National Standardization Organizations varies from one country to another. The most typical status is a private non-profit organization whose members are national business associations and companies, but sometimes the National Standardization Organization is a part of the Public Administration.

As stated in subclause 3.2, the European Standardization System guarantees that European Standards are identically adopted by all the National Standardization Organizations and any national conflicting standard is withdrawn, through the commitment of the Standstill Agreement. This means the national catalogues of standards have a big level of coherence across Europe and that the European Standardization System helps to achieve the goal of the single market objetive.

3.2 European Standardization Organizations

The European Standardization system plays a major role in the EU Single Market, enabling the free circulation of goods among 34 countries. The European standardization system relies on a single standard model. European standards are identically adopted by all the National Members and any national conflicting standard is withdrawn. European standards facilitate compliance with EU harmonization legislation, hence the entry and free circulation of goods in the EU Single Market, based on a set of requirements equally applicable in all Member States of the European Union.

European Standardization Organizations work closely with their international level counterparts, in order to avoid duplication of efforts and promote global relevance of standards. As a result of this, 31% of CEN standards are identical to ISO standards and 72% of CENELEC standards are identical to IEC standards.

CEN, CENELEC and ETSI have been officially recognized by the European Union (EU) and by the European Free Trade Association (EFTA) as European Standardization Bodies responsible for developing standards at European level (see Table 1).

Table 1. European Standardization Organizations

European Committee for Standardization	CEN is a non-profit association whose members are the national standards bodies of 33 European countries. It develops standards in fields not related to electrotechnology nor telecommunications. It is the counterpart at European level of ISO.
European Committee for Electrotechnical Standardization	CENELEC is a non-profit association whose members are the national standards bodies of 33 European countries. It develops standards in fields related to electrotechnology. It is the counterpart at European level of IEC.
European Telecommunications Standards Institute	ETSI is a non-profit organization with more than 800 member organizations worldwide. It develops standards for Information and Communications Technologies (ICT).

3.3 International Standardization Organizations

International Standardization Organizations develop worldwide applicable, market-driven standards, in a multi-stakeholder environment which ensures that a wide range of technical views are represented, including those relating to social and economic interests. While not subjected to a specific jurisdiction, International Standards have an important contribution to facilitating international trade. This contribution has been recognized by the World Trade Organization (WTO) and the organizations cited below follow the Code of Good Practice for the Preparation, Adoption and Application of Standards of the WTO Agreement on Technical Barriers to Trade. International Standards are based in the Global Relevance principle, the standards are useful through all the world.

Table 2 shows the International Standardization Organizations.

Table 2. International Standardization Organizations

International Standardization Organization	ISO is an independent, non-governmental international organization with a membership of 163 national standards bodies. ISO develops standards mainly in fields not related to electrotechnology nor telecommunications.
International Electrotechnical Commission	IEC is a not-for-profit, non-governmental organization with a membership of 84 national standards bodies. IEC develops standards in fields related to electrotechnology.

3.4 Standardization documents

The formal definition of a Standard is a "document, established by consensus and approved by a recognized body that provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context". These include requirements and/or recommendations in relation to products, systems, processes or services.

- European Standards are documents that have been ratified by one of the three European Standardization Organizations, CEN, CENELEC or ETSI; recognized as competent in the area of voluntary technical standardization as for the EU Regulation 1025/2012. As mentioned, the principle is one standard for all Europe. Their application is voluntary, but the adoption at national level as standard is mandatory.

- International Standards are documents that have been ratified by one of the two International Standardization Organizations, ISO or IEC. Their application is voluntary, and the adoption at national level is also voluntary.

All the standards, independently of their origin (national, european or international) are developed under the basis of consensus and approved by the members of the organization according to strict, defined procedures and strict drafting timeframes. Other types of documents are Technical Specifications (TS), Technical Reports (TR) and Workshop Agreements (WA), which have lower level of consensus and a faster drafting timeframe.

A summary of the characteristics of the different standardization documents can be found in Table 3.

Table 3. Characteristics of the different standardization documents

Type	International code	Eurepean code	National code	Main characteristics
Standard	ISO IEC	EN	UNE, NF, BS, DIN, etc. When adopting: UNE-EN, NF-EN, UNE-ISO, NF-ISO, etc.	• Elaboration: 3 years • 2 steps of member approval • European: compulsory national adoption • Revision: every 5 years
Technical Specification	ISO/TS IEC/TS	CEN/TS CLC/TS	When adopting: UNE-CEN/TS, NF-CEN/TS, UNE-ISO/TS, NF-ISO/TS, etc.	• Elaboration: 21 months • 1 step of member approval or internal approval in TC • European: optional national adoption • Revision: at 3 years (upgrading to EN or deletion)
Technical Report	ISO/TR IEC/TR	CEN/TR CLC/TR	When adopting: UNE-CEN/TR, NF-CEN/TR, UNE-ISO/TR, NF-ISO/TR, etc.	• Elaboration: free timeframe • Internal approval in TC • European: optional national adoption • No revision required
Workshop Agreement	IWA	CWA	Variable	• Elaboration: free timeframe (usually few months) • Internal approval in the Workshop • European: optional national adoption • Revision: at 3 years (upgrading to EN or deletion)

There is also agreements established between European and International Organizations in order to avoid duplication of efforts and promote global relevance of standards, which allows to adopt or develop in parallel each other's standards with the same content and code. National standards could also be proposed as a base for new European or International standards. The following Figure 1 shows the possible tracks of the standards.

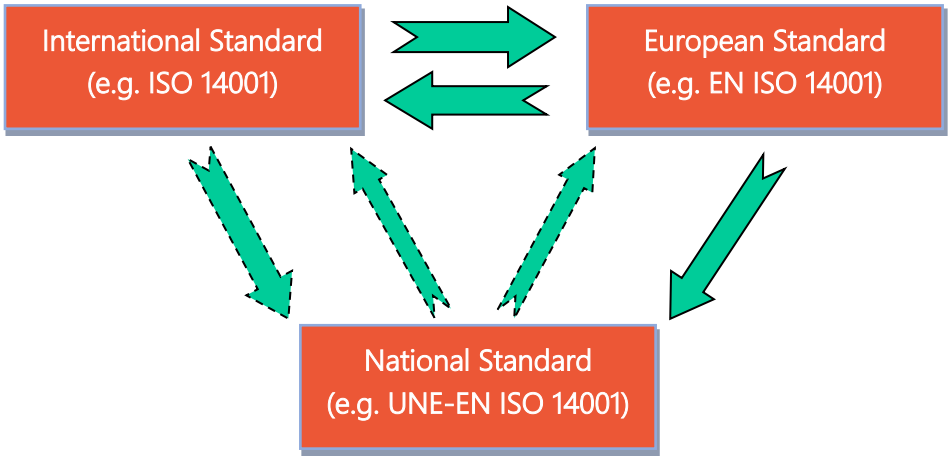

Figure 1. Possible tracks of standards adoption

Therefore, the code of any standard is the combination of the above mentioned issues, and could be explained as shown in Figure 2.

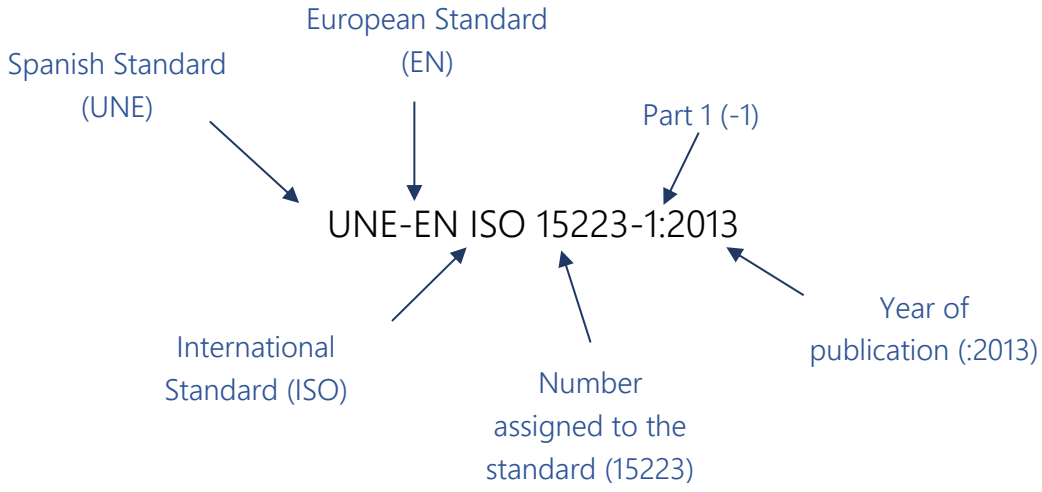

Figure 2. Example of identification of elements in the code of a standard

4. Regulatory framework

4.1 Directive 93/42/EEC

The current EU regulatory framework for the probe under the scope of MIRACLE's project is the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices, amended by Directive 2001/104/EC of the European Parliament and of the Council of 7 December 2001.

Directive 93/42/EEC covers medical devices and their accessories, having the consideration of medical device:

2. For the purposes of this Directive, the following definitions shall apply:
(a) 'medical device' means any instrument, apparatus, appliance, material or other article, whether used alone or in combination, including the software necessary for its proper application intended by the manufacturer to be used for human beings for the purpose of:
- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,
and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;

In Annex IX of the Directive it is given the definitions for the classification rules applicable to medical devices. The topic relevant for an arthroscopic are:

1.1. Duration
Transient: Normally intended for continuous use for less than 60 minutes.

1.2. Invasive devices
-Invasive device: A device which, in whole or in part, penetrates inside the body, either through a body orifice or through the surface of the body.
-Body orifice: Any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma.
- Surgically invasive device: An invasive device which penetrates inside the body through the surface of the body, with the aid or in the context of a surgical operation.
For the purposes of this Directive devices other than those referred to in the previous subparagraph and which produce penetration other than through an established body orifice, shall be treated as surgically invasive devices.

1.3 Reusable surgical instrument
Instrument intended for surgical use by cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar procedures, without connection to any active medical device and which can be reused after appropiate procedures have been carried out.

1.4. Active medical device
Any medical device operation of which depends on a source of electrical energy or any source of power other than that directly generated by the human body or gravity and which acts by converting this energy. Medical devices intended to transmit energy, substances or other elements between an active medical device and the patient, without any significant change, are not considered to be active medical devices.
...
1.6. Active device for diagnosis
Any active medical device, whether used alone or in combination with other medical devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities.

And the applicable Classification rules is:

2.2. Rule 6
All surgically invasive devices intended for transient use are in Class IIa unless they are:
- intended specifically to diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class III,
- reusable surgical instruments, in which case they are in Class I,
- intended to supply energy in the form of ionizing radiation in which case they are in Class IIb,
- intended to have a biological effect or to be wholly or mainly absorbed in which case they are in Class IIb,
- intended to administer medicines by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application, in which they are in Class IIb.

According to the following classification, arthroscopic probes are a Class IIa medical device.

Once the classification is done, the Directive specifies:

- The requirements to be fullfilled by the medical device.
- The evaluation of conformity applicable to the medical device.

Both the medical device requirements and the evaluation of conformitye has direct relation with European standardization. The relationship between standardardization and legislation at European level has been developed in accordance with the so-called 'New Approach' to

technical harmonization and standards, which was introduced in 1985. Directive 93/42/EEC is under this approach.

The principles of the New Approach are:

- The European Union adopts legislation (EU Directives) that defines essential requirements - in relation to safety and other aspects of public interest - which should be satisfied by products and services being sold in the Single Market;

- The European Commission issues standardization requests (Mandates) to the European Standardization Organizations (CEN, CENELEC and ETSI), which are responsible for preparing technical standards and specifications that facilitate compliance with these essential requirements;

- Public authorities must recognize that all products manufactured (and services provided) in accordance with harmonised standards are presumed to conform to the essential requirements as defined by the relevant EU legislation;

- European Standards remain voluntary and there is no legal obligation to apply them. Any producer (or service provider) who chooses not to follow a harmonised standard is obliged to prove that their products (or services) conform to the essential requirements;

- Around 25% of European Standards published by CEN have been developed in response to standardization requests (Mandates) issued by the European Commission.

In relation to medical devices, Directive 93/42/EEC states in its Article 5:

Article 5
Reference to standards
1. Member States shall presume compliance with the essential requirements referred to in Article 3 in respect of devices which are in conformity with the relevant national standards adopted pursuant to the harmonized standards the references of which have been publishes in the Official Journal of the European Communities; Member States shall publish the references of such national standards.
2. For the purposes of this Directive, reference to harmonized standards also includes the monographs of the European Pharmacopoeia notably on surgical sutures and on interaction between medicinal products and materials used in devices containing such medicinal products, the references of which have been published in the Official Journal of the European Communities.
3. If a Member State or the Commission considers that the harmonized standards do not entirely meet the essential requirements referred to in Article 3, the measures to be taken by the Member States with

regard to these standards and the publication referred to in paragraph 1 of this Article shall be adopted by the procedure defined in Article 6 (2).

It is important to note that in this moment no specific product standard for any kind of arthrocopic probe, neither for any arthroscopic instrument, has been published or is under development. Nevertheless, there are complementary and support standards that should be taken into account.

In the following link it can be found the list of harmonised standards giving presumption of conformity with Directive 93/42/EEC, the text of the Directive and some informative material.

http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/medical-devices_en

Additional information: https://ec.europa.eu/growth/sectors/medical-devices/guidance_en

4.2 Regulation 2017/745

On May 2017 the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices was published. This Regulation has entered into force in June 2017 and shall be applied from 26th May 2020.

The main definitions dealing with the MIRACLE projects are:

Article 2
Definitions
For the purposes of this Regulation, the following definitions apply:
(1) 'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:
— diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
— diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
— investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
— providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations,
and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.
The following products shall also be deemed to be medical devices:

— devices for the control or support of conception;
— products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in Article 1(4) and of those referred to in the first paragraph of this point.
…
(4) 'active device' means any device, the operation of which depends on a source of energy other than that generated by the human body for that purpose, or by gravity, and which acts by changing the density of or converting that energy. Devices intended to transmit energy, substances or other elements between an active device and the patient, without any significant change, shall not be deemed to be active devices.
Software shall also be deemed to be an active device;

In Annex VIII of the Regulation, the new classification applicable to medical devices is provided. The topics relevant for an arthroscopic probe are:

1. DURATION OF USE
1.1. 'Transient' means normally intended for continuous use for less than 60 minutes.
…
2. INVASIVE AND ACTIVE DEVICES
2.1. 'Body orifice' means any natural opening in the body, as well as the external surface of the eyeball, or any permanent artificial opening, such as a stoma.
2.2. 'Surgically invasive device' means:
(a) an invasive device which penetrates inside the body through the surface of the body, including through mucous membranes of body orifices with the aid or in the context of a surgical operation; and
(b) a device which produces penetration other than through a body orifice.
…
2.5. 'Active device intended for diagnosis and monitoring' means any active device used, whether alone or in combination with other devices, to supply information for detecting, diagnosing, monitoring or treating physiological conditions, states of health, illnesses or congenital deformities.

In relation to the arthroscopic probes under the MIRACLE project, the classification remains the same as in Directive 93/42/EEC, they are considered class IIa.

6.2. Rule 10
Active devices intended for diagnosis and monitoring are classified as class IIa:
— if they are intended to supply energy which will be absorbed by the human body, except for devices intended to illuminate the patient's body, in the visible spectrum, in which case they are classified as class I;
— if they are intended to image in vivo distribution of radiopharmaceuticals; or
— if they are intended to allow direct diagnosis or monitoring of vital physiological processes, unless they are specifically intended for monitoring of vital physiological parameters and the nature of

variations of those parameters is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of the central nervous system, or they are intended for diagnosis in clinical situations where the patient is in immediate danger, in which cases they are classified as class IIb.
Active devices intended to emit ionizing radiation and intended for diagnostic or therapeutic radiology, including interventional radiology devices and devices which control or monitor such devices, or which directly influence their performance, are classified as class IIb.
6.3. Rule 11
Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa, except if such decisions have an impact that may cause:
— death or an irreversible deterioration of a person's state of health, in which case it is in class III; or
— a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class IIb.
Software intended to monitor physiological processes is classified as class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class IIb. All other software is classified as class I.

And finally, although this new legislative document is a Regulation and not a Directive, it follows the principle of the New Approach, and it states:

Whereas:
…
(22) To recognise the important role of standardisation in the field of medical devices, compliance with harmonised standards as defined in Regulation (EU) No 1025/2012 of the European Parliament and of the Council (2) should be a means for manufacturers to demonstrate conformity with the general safety and performance requirements and other legal requirements, such as those relating to quality and risk management, laid down in this Regulation.

And a specific article:

Article 8
Use of harmonised standards
1.Devices that are in conformity with the relevant harmonised standards, or the relevant parts of those standards, the references of which have been published in the Official Journal of the European Union, shall be presumed to be in conformity with the requirements of this Regulation covered by those standards or parts thereof.
The first subparagraph shall also apply to system or process requirements to be fulfilled in accordance with this Regulation by economic operators or sponsors, including those relating to quality

management systems, risk management, post-market surveillance systems, clinical investigations, clinical evaluation or post-market clinical follow-up ('PMCF').
References in this Regulation to harmonised standards shall be understood as meaning harmonised standards the references of which have been published in the Official Journal of the European Union.
2.References in this Regulation to harmonised standards shall also include the monographs of the European Pharmacopoeia adopted in accordance with the Convention on the Elaboration of a European Pharmacopoeia, in particular on surgical sutures and on interaction between medicinal products and materials used in devices containing such medicinal products, provided that references to those monographs have been published in the Official Journal of the European Union.

For the moment, as the Regulation has been recently published, there are no harmonised standards and the ones under Directive 93/42/EEC are still valid.

In the following link the complete text and additional information about Regulation 2017/745 can be found:

https://ec.europa.eu/growth/sectors/medical-devices/regulatory-framework_en#new_regulations

During the development of the MIRACLE project Regulation 2017/745 will enter into force and its deployment will move along. In the next Deliverables, updated informateion about Regulation 2017/745 and standardization will be provided.

5. Methodology used to prepare the report

This document presents the standardization activity found relevant for the MIRACLE project. In order to structure the search, two kind of searches have been made: key-words and International Classification of Standards (ICS).

5.1. Product description

As defined in the MIRACLE Objectives, an innovative and easy-to-operate mid-infrared (MIR) imaging-probe to be used during minimally invasive arthroscropic surgery enabling in-depth diagnosis of articular cartilage will be implemented.

This probe will be assembled in a set of associated equipment:

- Lasers and light sources.
- Software.
- Electrical components.
- Interface and displays.
- Data processing and analysis.
- Sterilizing requirements.
- etc.

The specifications and requirements of the MIR-ATR arthroscopic probe can be found in Deliverable D1.7.

5.2. Key-words

The first search has been made looking for key-words in the title and scope of the documents. In Table 4 the list of concepts prepared by UNE to act a starting point for the identification of standardization areas can be found in Table 4.

Table 4. List of key-words acting as starting point for the identification of standardization areas

Key-word
Medical equipment
Medical technologies
Electromedical equipment
Electromedical technologies

Sanitary equipment
Sanitary technologies
Sterilization
Desinfection
Information technologies
Optical fibres
ECM

5.3. International Classification for Standards (ICS)

The second search has been made looking for documents with defined ICS (International Classification for Standards) which is "intended to serve as a structure for catalogues of international, regional and national standards and other normative documents, and as a basis for standing-order systems for international, regional and national standards. It may also be used for classifying standards and normative documents in databases, libraries, etc."

Therefore, the relation between the ICS and the respective keywords has helped on the searching of the standards that could be references for the overall scope of the project and are within the scope of deliverable D1.16.

The ICS is a hierarchical classification which consists of three levels. Level 1 covers 40 fields of activity in standardization, e.g. medical equipment, IT applications in health care technology, agriculture, metallurgy. Each field has a two-digit notation, e.g.

01 GENERALITIES. TERMINOLOGY. STANDARDIZATION. DOCUMENTATION

The fields are subdivided into 392 groups (level 2). The notation of a group consists of the field notation and a three-digit group number, separated by a point, e.g.

01.040 Vocabularies

144 of the 392 groups are further divided into 909 sub-groups (level 3). The notation of a sub-group consists of the group notation and a two-digit number, separated by a point, e.g.

01.040.35 Information technologies

The searching of ICS is based in the relevant key-words given in Table 4.

Table 5. List of ICS acting as starting point for the identification of standardization areas

ICS	Description
11.020.01	Care. Quality and environmental management in health care
11.020.10	Care. Health care services in general
11.020.20	Medical. Medical science
11.020.99	Care. Other standards related to health care in general
11.040.01	Medical. Medical equipment in general
11.040.30	Instruments. Surgical instruments and materials
11.040.55	Diagnostic. Diagnostic equipment
11.040.99	Medical. Other medical equipment
11.080.01	Disinfection. Sterilization and disinfection in general
11.080.99	Disinfection. Other standards related to sterilization and disinfection
11.100.20	Biological. Biological evaluation of medical devices
35.030	Security. IT Security
35.240.80	Care. IT applications in health care technology

6. List of relevant standards and standardards under development

6.1. Technical Committes identification

Subsequent to the application of the previous methodology explained in 4.2 and 4.3, a list of relevant standards has been obtained.

In order to present the list in a coherent and understandable way, the list of relevant standard has been gouped by the responsible Technical Committee.

Table 6 shows the list of identified Technical Committees (European and International).

Table 6. List of ICS acting as starting point for the identification of standardization areas

European TC	Title
CEN/TC 204	Sterilization of medical devices
CEN/TC 206	Biological evaluation of medical devices
CEN/TC 251	Health informatics
CEN/TC 257	Symbols and information provided with medical devices and nomenclature for regulatory data exange (disbanded)
CEN/TC 450	Patient involvement in person-centred care
CEN/WS SATORI	Ethics assessment of research and innovation
CEN-CLC/JTC 3	Quality management and corresponding general aspects for medical devices
CEN-CLC ABHS	Advisory Board for Health Standards
CLC/TC 62	Electromedical equipment
CLC/TC 86A	Optical fibres and optical fibre cables
CLC/TC 106X	Electromagnetic fields in human environment
International TC	**Title**
ISO/TC 170	Surgical instruments
ISO/TC 194	Biological and clinical evaluation of medical devices
ISO/TC 198	Sterilization of health-care products
ISO/TC 210	Quality management and corresponding general aspects for medical devices
ISO/TC 215	Health informatics
ISO/TC 262	Risk management
ISO/TC 276	Biotechnology
IEC/TC 62	Electrical equipment in medical practice
IEC/TC 86A	Fibres and cables
IEC/TC 106	Methods for the assessment of electric, magnetic and electromagnetic fields associated with human exposure

6.2. Identified Standards sorted by Technical Committee

CEN/TC 204 Sterilization of medical devices

Scope:

Standardization in the field of validation and monitoring of sterilization processes as used in manufacturing of medical devices.

Table 7. List of CEN/TC 204 standards and standards under development

Standard reference	Title	Status
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 556-2:2015	Sterilization of medical devices - Requirements for medical devices to be designated ''STERILE" - Part 2: Requirements for aseptically processed medical devices	
EN ISO 11135:2014	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014)	Under development: Amendment prA1
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)	Under development: Amendment prA1
EN ISO 11137-2:2015	Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:2013)	Under development: prEN ISO 11727-2
EN ISO 11137-3:2017	Sterilization of health care products - Radiation - Part 3: Guidance on dosimetric aspects of development, validation and routine control (ISO 11137-3:2017)	
EN ISO 11737-1:2018	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018)	
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)	

CEN ISO/TS 13004:2014	Sterilization of health care products - Radiation - Substantiation of selected sterilization dose: Method VDmaxSD (ISO/TS 13004:2013)	
EN ISO 13408-1:2015	Aseptic processing of health care products - Part 1: General requirements (ISO 13408-1:2008, including Amd 1:2013)	
EN ISO 13408-2:2018	Aseptic processing of health care products - Part 2: Sterilizing filtration (ISO 13408-2:2018)	
EN ISO 13408-3:2011	Aseptic processing of health care products - Part 3: Lyophilization (ISO 13408-3:2006)	
EN ISO 13408-4:2011	Aseptic processing of health care products - Part 4: Clean-in-place technologies (ISO 13408-4:2005)	
EN ISO 13408-5:2011	Aseptic processing of health care products - Part 5: Sterilization in place (ISO 13408-5:2006)	
EN ISO 13408-6:2011 + Amendment A1:2013	Aseptic processing of health care products - Part 6: Isolator systems (ISO 13408-6:2005)	Under development: prEN ISO 13408-6
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)	
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)	
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)	
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)	Under development: prEN ISO 17665-1
CEN ISO/TS 17665-2:2009	Sterilization of health care products - Moist heat - Part 2: Guidance on the application of ISO 17665-1 (ISO/TS 17665-2:2009)	
EN ISO 20857:2013	Sterilization of health care products - Dry heat - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 20857:2010)	
EN ISO 25424:2011	Sterilization of medical devices - Low temperature steam	Under

	and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 25424:2009)	development: prEN ISO 25424

CEN/TC 206 Biological evaluation of medical devices

Scope:

Standardization of the approach to biological and clinical evaluation of medical and dental materials and devices together with standardization of biological test methods applicable to those materials and devices as well as good clinical practice principles to clinical investigations in humans of those devices.

Table 8. List of CEN/TC 206 standards and standards under development

Standard reference	Title	Status
EN ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)	Revision: FprEN ISO 10993-1
EN ISO 10993-2:2006	Biological evaluation of medical devices - Part 2: Animal welfare requirements (ISO 10993-2:2006)	
EN ISO 10993-3:2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2014)	
EN ISO 10993-4:2017	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood (ISO 10993-4:2017)	
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)	
EN ISO 10993-6:2016	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation (ISO 10993-6:2016)	
EN ISO 10993-7:2008	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (ISO 10993-7:2008)	Under development amendment: EN ISO 10993-7/prA1
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)	Revision: prEN ISO 10993-9
EN ISO 10993-	Biological evaluation of medical devices - Part 10: Tests for	Revision:

10:2013	irritation and skin sensitization (ISO 10993-10:2010)	prEN ISO 10993-10
EN ISO 10993-11:2018	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017)	
EN ISO 10993-12:2012	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2012)	Revision: prEN ISO 10993-12
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)	
EN ISO 10993-14:2009	Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products from ceramics (ISO 10993-14:2001)	
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)	Revision: prEN ISO 10993-15
EN ISO 10993-16:2017	Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables (ISO 10993-16:2017)	
EN ISO 10993-17:2009	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances (ISO 10993-17:2002)	
EN ISO 10993-18:2009	Biological evaluation of medical devices - Part 18: Chemical characterization of materials (ISO 10993-18:2005)	Revision: prEN ISO 10993-18
EN ISO 14155:2011	Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2011)	Revision: prEN ISO 14155
EN ISO 22442-1:2015	Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk management (ISO 22442-1:2015)	Revision: prEN ISO 22442-1
EN ISO 22442-2:2015	Medical devices utilizing animal tissues and their derivatives - Part 2: Controls on sourcing, collection and handling (ISO 22442-2:2015)	Revision: prEN ISO 22442-2
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)	

CEN/TC 251 Health informatics

Scope:

Standardization in the field of Health Information and Communications Technology (ICT) to achieve compatibility and interoperability between independent systems and to enable modularity. This includes requirements on health information structure to support clinical and administrative procedures, technical methods to support interoperable systems as well as requirements regarding safety, security and quality.

Table 9. List of CEN/TC 251 standards and standards under development

Standard reference	Title	Status
EN 1068:2005	Health informatics - Registration of coding systems	
CR 1350:1993	Investigation of syntaxes for existing interchange formats to be used in health care	
EN 12264:2005	Health informatics - Categorial structures for systems of concepts	
EN 12381:2005	Health informatics - Time standards for healthcare specific problems	Revision: prEN 12381
ENV 12443:1999	Medical Informatics - Healthcare Information Framework (HIF)	
EN 12435:2006	Health informatics - Expression of results of measurements in health sciences	
CR 12587:1996	Medical Informatics - Methodology for the development of healthcare messages	
ENV 12612:1997	Medical informatics - Messages for the exchange of healthcare administrative information	
EN 13606-2:2007	Health informatics - Electronic health record communication - Part 2: Archetypes interchange specification	Revision: prEN 13606-2
EN 13606-3:2008	Health informatics - Electronic health record communication - Part 3: Reference archetypes and term lists	Revision: prEN 13606-3
EN 13606-4:2007	Health informatics - Electronic health record communication - Part 4: Security	Revision: prEN 13606-4
EN 13609-1:2005	Health informatics - Messages for maintenance of supporting information in healthcare systems - Part 1: Updating of coding schemes	Revision: prEN 13606-5
ENV 13609-2:2000	Health informatics - Messages for maintenance of supporting information in healthcare systems - Part 2: Updating of medical laboratory-specific information	

CR 14301:2002	Health informatics - Framework for security protection of healthcare communication	
CR 14302:2002	Health informatics - Framework for security requirements for intermittently connected devices	
EN 14822-1:2005	Health informatics - General purpose information components - Part 1: Overview	
EN 14822-2:2005	Health informatics - General purpose information components - Part 2: Non-clinical	
EN 14822-3:2005	Health informatics - General purpose information components - Part 3: Clinical	
CEN/TS 14822-4:2005	Health informatics - General purpose information components - Part 4: Message headers	
EN 14484:2003	Health informatics - International transfer of personal health data covered by the EU data protection directive - High level security policy	
EN 14485:2003	Health informatics - Guidance for handling personal health data in international applications in the context of the EU data protection directive	
CEN/TR 15212:2006	Health informatics - Vocabulary - Maintenance procedure for a web-based terms and concepts database	
CEN/TR 15253:2005	Health informatics - Quality of service requirements for health information interchange	
CEN/TR 15299:2006	Health informatics - Safety procedures for identification of patients and related objects	
CEN/TR 15300:2006	Health informatics - Framework for formal modelling of healthcare security policies	
CEN/TR 15872:2014	Health informatics - Guidance on patient identification and cross-referencing of identities	
prEN 17269	Health informatics - The Patient Summary for Unscheduled, Cross-border Care	Under development
FprCEN/TS 17288	Health informatics - The International Patient Summary: Guidance for European Implementation Technical Specification	Under development
EN ISO 1828:2012	Health informatics - Categorial structure for terminological systems of surgical procedures (ISO 1828:2012)	
EN ISO 10781:2015	Health Informatics - HL7 Electronic Health Records-System Functional Model, Release 2 (EHR FM) (ISO 10781:2015)	
EN ISO 12052:2017	Health informatics - Digital imaging and communication in medicine (DICOM) including workflow and data	

	management (ISO 12052:2017)	
EN ISO 12967-1:2011	Health informatics - Service architecture - Part 1: Enterprise viewpoint (ISO 12967-1:2009)	Revision: prEN ISO 12967-1
EN ISO 12967-2:2011	Health informatics - Service architecture - Part 2: Information viewpoint (ISO 12967-2:2009)	Revision: prEN ISO 12967-2
EN ISO 12967-3:2011	Health informatics - Service architecture - Part 3: Computational viewpoint (ISO 12967-3:2009)	Revision: prEN ISO 12967-3
EN ISO 13119:2012	Health informatics - Clinical knowledge resources - Metadata (ISO 13119:2012)	
EN ISO 13120:2013	Health informatics - Syntax to represent the content of healthcare classification systems - Classification Markup Language (ClaML) (ISO 13120:2013)	Revision: prEN ISO 13120
EN ISO 13606-1:2012	Health informatics - Electronic health record communication - Part 1: Reference model (ISO 13606-1:2008)	Revision: prEN ISO 13606-1
EN ISO 13606-5:2010	Health informatics - Electronic health record communication - Part 5: Interface specification (ISO 13606-5:2010)	
EN ISO 13940:2016	Health informatics - System of concepts to support continuity of care (ISO 13940:2015)	
EN ISO 16278:2016	Health informatics - Categorial structure for terminological systems of human anatomy (ISO 16278:2016)	
EN ISO 17523:2016	Health informatics - Requirements for electronic prescriptions (ISO 17523:2016)	
EN ISO 21090:2011	Health Informatics - Harmonized data types for information interchange (ISO 21090:2011)	
EN ISO 21091:2013	Health informatics - Directory services for healthcare providers, subjects of care and other entities (ISO 21091:2013)	
EN ISO 21298:2017	Health informatics - Functional and structural roles (ISO 21298:2017, Corrected version 2017-04)	
EN ISO 22600-1:2014	Health informatics - Privilege management and access control - Part 1: Overview and policy management (ISO 22600-1:2014)	
EN ISO 22600-2:2014	Health informatics - Privilege management and access control - Part 2: Formal models (ISO 22600-2:2014)	

EN ISO 22600-3:2014	Health informatics - Privilege management and access control - Part 3: Implementations (ISO 22600-3:2014)	
EN ISO 25237:2017	Health informatics - Pseudonymization (ISO 25237:2017)	
EN ISO 27799:2016	Health informatics - Information security management in health using ISO/IEC 27002 (ISO 27799:2016)	

CEN/TC 257 Symbols and information provided with medical devices and nomenclature for regulatory data exange (disbanded)

Scope:

Standardization of labelling requirements and symbols used in labelling in the field of medical devices and in SC 1 standardization of the identification, coding, nomenclature and data sets for medical devices to facilitate regulatory data exchange.

Table 10. List of CEN/TC 257 standards and standards under development

Standard reference	Title	Status
ENV 13004:1999	Nomenclature system for medical devices for the purposes of regulatory data exchange - Recommendations for an interim system and rules for a future system	

CEN/TC 450 Patient involvement in person-centred care

Scope:

Primarily to develop standards that specify patient involvement in health care services, with the aim to create favourable structural conditions for person-centred care in partnership with the healthcare professional.

Table 11. List of CEN/TC 450 standards and standards under development

Standard reference	Title	Status
WI 450001	Patient involvement in health care – Minimum requirements for person-centred care	Under development

CEN/WS SATORI Ethics assessment of research and innovation

Scope:

The CEN Workshop Agreement sets requirements and provides guidelines for ethics assessment of research and innovation. It aims to improve the quality of ethics assessment and harmonize ethics assessment practices. The CWA applies to organizations or agents involved in performing, commissioning, funding or assessing research and innovation, and therefore have a responsibility to address ethical issues.

Table 12. List of CEN/WS SATORI standards and standards under development

Standard reference	Title	Status
CWA 17145-1:2017	Ethics assessment for research and innovation - Part 1: Ethics committee	
CWA 14145-2:2017	Ethics assessment for research and innovation - Part 2: Ethical impact assessment framework	

CEN-CLC/JTC 3 Quality management and corresponding general aspects for medical devices

Scope:

The objective of the joint Technical Committee is to contribute to, and where necessary draft, suitable standards for "Quality management and corresponding general aspects for medical devices" that are applicable internationally and relevant to the essential requirements of EU Directives. The joint Technical Committee closely cooperates with ISO/TC 210 'Quality management and corresponding general aspects for medical devices' in the development of standards and revisions. The objective of the joint Technical Committee is to contribute to a further global harmonization of standards in close co-operation with ISO/TC 210. In principle the standards are drafted by ISO/TC 210 under the Vienna agreement with ISO-lead, including the joint work programme with IEC/SC 62. The joint Technical Committee will liaise with other Technical Committees - to achieve a coherent set of horizontal and product standards; - to minimize the necessity for additional European requirements; - to advise on aspects concerning quality management and risk management to ensure an optimal use of EN ISO 13485 and EN ISO 14971.

Table 13. List of CEN-CLC/JTC 3 standards and standards under development

Standard reference	Title	Status
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical devices	
CR 13217:1998	Nomenclature system for medical devices for the purpose of regulatory data exchange - Rationale	
CEN/TR 15133:2005	Nomenclature - Collective terms and codes for groups of medical devices	
EN 15986:2011	Symbol for use in the labelling of medical devices - Requirements for labelling of medical devices containing phthalates	
CEN CLC/TR 14060:2014	Medical device traceability enabled by unique device identification (UDI)	
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)	
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)	Revision: prEN ISO 14971
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)	
prCEN ISO/TR 20416	Medical devices - Post-market surveillance for manufacturers	Under development

CEN-CLC/ABHS Advisory Board for Health Standards

Scope:

The Mission of the Advisory Board for Healthcare Standards (ABHS) is to provide strategic and well-informed advice on matters relating to Healthcare Standardization in the European Economic Area (EEA) to CEN and CENELEC and their Technical Boards (BTs).

Originally created within the CEN framework, ABHS extended its scope in 2012 to the electrotechnical field by becoming also a CENELEC body. ETSI (the European Telecommunications Standards Institute) also participates actively in the ABHS activities.

On the basis of the discussions within ABHS, the group provides the CEN and CENELEC Technical Boards (CEN/BT and CENELEC/BT – the technical policy-making bodies) with advice, information, opinions and suggestions that may guide CEN/BT and CENELEC/BT in their political decisions.

CLC/TC 62 Electromedical equipment

Scope:

To establish harmonised standards and other publications concerning electrical equipment, electrical systems and software used in healthcare and their effects on patients, operators, other persons and the environment.

NOTE: This scope includes items that are also within the scopes of other committees and will be addressed through cooperation. Attention will focus on safety and performance (e.g. radiation protection, data security, data integrity, data privacy and environmental aspects) and will contribute to regulatory frameworks. Healthcare includes medical practice as well as emergency medical services, homecare, and support of persons with disabilities in their daily lives (i.e. Ambient Assisted Living).

Table 14. List of CLC/TC 62 standards and standards under development

Standard reference	Title	Status
EN 60601-1:1990 + Amendments A1:1993, A2:1995	Medical electrical equipment - Part 1: General requirements for safety	Under development amendment: EN 60601-1/prA2
EN 60601-1:2006 + Amendments A1:2013, A12:2014	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	
EN 60601-1-1:2001	Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems	
EN 60601-1-2:2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	
EN 60601-1-2:2015	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance -	Under development

	Collateral Standard: Electromagnetic disturbances - Requirements and tests	amendment: EN 60601-1-2/prA1
EN 60601-1-4:1996 + Amendment A1:1999	Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems	
EN 60601-1-6:2010+ Amendment A1:2015	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	Under development amendment: EN 60601-1-2/prA2
EN 60601-1-8:2007+ Amendment A1:2013, A11:2017	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	Under development amendment: EN 60601-1-8/prA2
EN 60601-1-9:2008+ Amendment A1:2013	Medical electrical equipment - Part 1-9: General requirements for basic safety and essential performance - Collateral Standard: Requirements for environmentally conscious design	
EN 60601-1-10:2008 + Amendment A1:2015	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	Under development amendment: EN 60601-10/prA2
EN 60601-1-11:2015	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	Under development amendment: EN 60601-11/prA1
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	
EN 60601-2-64:2015	Medical electrical equipment - Part 2-64: Particular requirements for the basic safety and essential performance of light ion beam medical electrical equipment	
EN 60789:2005	Medical electrical equipment - Characteristics and test conditions of radionuclide imaging devices - Anger type	

	gamma cameras	
EN 61223-2-4:1994	Evaluation and routine testing in medical imaging departments - Part 2-4: Constancy tests - Hard copy cameras	
EN 61223-2-5:1994	Evaluation and routine testing in medical imaging departments - Part 2-5: Constancy tests - Image display devices	
EN 61303:1995	Medical electrical equipment - Radionuclide calibrators - Particular methods for describing performance	
EN 62304:2006+ Amendment A1:2015	Medical device software - Software life-cycle processes	Revision: prEN 62304
EN 62353:2014	Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment	
EN 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices	Under development amendment: EN 62366-1/prA1
EN 62563-1:2010+ Amendment A1:2016	Medical electrical equipment - Medical image display systems - Part 1: Evaluation methods	
EN 80001-1:2011	Application of risk management for IT-networks incorporating medical devices - Part 1: Roles, responsibilities and activities	Revision: prEN 80001-1
EN 82304-1:2017	Health Software - Part 1: General requirements for product safety	
EN IEC 80601-2-71:2018	Medical electrical equipment - Part 2-71: Particular requirements for the basic safety and essential performance of functional near-infrared spectroscopy (NIRS) equipment	

CLC/TC 86A Optical fibres and optical fibre cables

Scope:

To prepare and maintain specifications for optical fibres and optical fibre calbes, excluding image transmission types.

Table 15. List of CLC/TC 86A standards and standards under development

Standard reference	Title	Status
CLC/TR 50510:2012	Fibre optic access to end-user - A guideline to building of FTTX fibre optic network	
EN 50551-1:2011	Simplex and duplex cables for use in terminated cable assemblies - Part 1: Blank Detail Specification and minimum requirements	Revision: prEN 50551-1
EN 50551-2:2013	Simplex and duplex cables to be used for cords - Part 2: Detailed specification and minimum requirements for a 3,0 mm simplex ruggedised single mode fibre cable to be used for patchcords/cords category U	
EN 50582:2016	Procedure to assess the circuit integrity of optical fibres in a cable under resistance to fire testing	
CLC/TS 50621:2016	Guideline for the repair of damaged installed optical fibre cables and microducts	
EN 60793-1-1:2008	Optical fibres - Part 1-1: Measurement methods and test procedures - General and guidance	
EN 60793-1-1:2017	Optical fibres - Part 1-1: Measurement methods and test procedures - General and guidance	
EN 60793-1-20:2014	Optical fibres - Part 1-20: Measurement methods and test procedures - Fibre geometry	
EN 60793-1-21:2002	Optical fibres - Part 1-21: Measurement methods and test procedures - Coating geometry	
EN 60793-1-22:2002	Optical fibres - Part 1-22: Measurement methods and test procedures - Length measurement	
EN 60793-1-30:2011	Optical fibres - Part 1-30: Measurement methods and test procedures - Fibre proof test	
EN 60793-1-31:2010	Optical fibres - Part 1-31: Measurement methods and test procedures - Tensile strength	
EN 60793-1-32:2010	Optical fibres - Part 1-32: Measurement methods and test procedures - Coating strippability	Revision: prEN 60793-1-32
EN 60793-1-33:2002	Optical fibres - Part 1-33: Measurement methods and test procedures - Stress corrosion susceptibility	
EN 60793-1-33:2017	Optical fibres - Part 1-33: Measurement methods and test procedures - Stress corrosion susceptibility	
EN 60793-1-34:2006	Optical fibres - Part 1-34: Measurement methods and test procedures - Fibre curl	
EN 60793-1-	Optical fibres - Part 1-40: Attenuation measurement	Revision:

40:2003	methods	prEN 60793-1-40
EN 60793-1-41:2010	Optical fibres - Part 1-41: Measurement methods and test procedures - Bandwidth	
EN 60793-1-42:2013	Optical fibres - Part 1-42: Measurement methods and test procedures - Chromatic dispersion	
EN 60793-1-43:2015	Optical fibres - Part 1-43: Measurement methods and test procedures - Numerical aperture measurement	
EN 60793-1-44:2011	Optical fibres - Part 1-44: Measurement methods and test procedures - Cut-off wavelength	
EN 60793-1-45:2003	Optical fibres - Part 1-45: Measurement methods and test procedures - Mode field diameter	
EN IEC 60793-1-45:2018	Optical fibres - Part 1-45: Measurement methods and test procedures - Mode field diameter	
EN IEC 60793-1-46:2002	Optical fibres - Part 1-46: Measurement methods and test procedures - Monitoring of changes in optical transmittance	
EN 60793-1-47:2009	Optical fibres - Part 1-47: Measurement methods and test procedures - Macrobending loss	
EN IEC 60793-1-47:2018	Optical fibres - Part 1-47: Measurement methods and test procedures - Macrobending loss	
EN 60793-1-48:2007	Optical fibres - Part 1-48: Measurement methods and test procedures - Polarization mode dispersion	
EN IEC 60793-1-48:2017	Optical fibres - Part 1-48: Measurement methods and test procedures - Polarization mode dispersion	
EN 60793-1-49:2006	Optical fibres - Part 1-49: Measurement methods and test procedures - Differential mode delay	Revision: prEN 60793-1-49
EN 60793-1-50:2015	Optical fibres - Part 1-50: Measurement methods and test procedures - Damp heat (steady state) tests	
EN 60793-1-51:2014	Optical fibres - Part 1-51: Measurement methods and test procedures - Dry heat (steady state) tests	
EN 60793-1-52:2014	Optical fibres - Part 1-52: Measurement methods and test procedures - Change of temperature tests	
EN 60793-1-53:2014	Optical fibres - Part 1-53: Measurement methods and test procedures - Water immersion tests	
EN 60793-1-54:2013	Optical fibres - Part 1-54: Measurement methods and test procedures - Gamma irradiation	
EN IEC 60793-1-54:2018	Optical fibres - Part 1-54: Measurement methods and test procedures - Gamma irradiation	

EN IEC 60793-1-60:2017	Optical fibres - Part 1-60: Measurement methods and test procedures - Beat length	
EN IEC 60793-1-61:2017	Optical fibres - Part 1-61: Measurement methods and test procedures - Polarization crosstalk	
EN 60793-2-10:2011	Optical fibres - Part 2-10: Product specifications - Sectional specification for category A1 multimode fibres	Revision: prEN 60793-2-10
EN 60793-2-10:2016	Optical fibres - Part 2-10: Product specifications - Sectional specification for category A1 multimode fibres	
EN 60793-2-10:2017	Optical fibres - Part 2-10: Product specifications - Sectional specification for category A1 multimode fibres	
EN 60793-2-20:2009	Optical fibres - Part 2-20: Product specifications - Sectional specification for category A2 multimode fibres	
EN 60793-2-20:2016	Optical fibres - Part 2-20: Product specifications - Sectional specification for category A2 multimode fibres	
EN 60793-2-30:2013	Optical fibres - Part 2-30: Product specifications - Sectional specification for category A3 multimode fibres	
EN 60793-2-30:2015	Optical fibres - Part 2-30: Product specifications - Sectional specification for category A3 multimode fibres	
EN 60793-2-40:2011	Optical fibres - Part 2-40: Product specifications - Sectional specification for category A4 multimode fibres	
EN 60793-2-40:2016	Optical fibres - Part 2-40: Product specifications - Sectional specification for category A4 multimode fibres	
EN 60793-2-50:2013	Optical fibres - Part 2-50: Product specifications - Sectional specification for class B single-mode fibres	Revision: prEN 60793-2-50
EN 60793-2-50:2016	Optical fibres - Part 2-50: Product specifications - Sectional specification for class B single-mode fibres	
EN 60793-2-60:2016	Optical fibres - Part 2-60: Product specifications - Sectional specification for category C single-mode intraconnection fibres	
EN 60793-2-70:2017	Optical fibres - Part 2-70: Product specifications - Sectional specification for polarization-maintaining fibres	
EN 60793-2:2012	Optical fibres - Part 2: Product specifications – General	
EN 60793-2:2016	Optical fibres - Part 2: Product specifications – General	
EN 60794-1-1:2011	Optical fibre cables - Part 1-1: Generic specification - General	
EN 60794-1-1:2016	Optical fibre cables - Part 1-1: Generic specification - General	
EN 60794-1-2:2014	Optical fibre cables - Part 1-2: Generic specification - Cross reference table for optical cable test procedures	

EN 60794-1-2:2017	Optical fibre cables - Part 1-2: Generic specification - Cross reference table for optical cable test procedures	
EN 60794-1-3:2017	Optical fibre cables - Part 1-3: Generic specification - Optical cable elements	
EN 60794-1-20:2014	Optical fibre cables - Part 1-20: Generic specification - Basic optical cable test procedures - General and definitions	
EN 60794-1-21:2015	Optical fibre cables - Part 1-21: Generic specification - Basic optical cable test procedures - Mechanical tests methods	Revision: prEN 60794-1-21
EN 60794-1-22:2012	Optical fibre cables - Part 1-22: Generic specification - Basic optical cable test procedures - Environmental test methods	
EN IEC 60794-1-22:2018	Optical fibre cables - Part 1-22: Generic specification - Basic optical cable test procedures - Environmental test methods	
EN 60794-1-23:2012	Optical fibre cables - Part 1-23: Generic specification - Basic optical cable test procedures - Cable element test methods	Revision: prEN 60794-1-23
EN 60794-1-24:2014	Optical fibre cables - Part 1-24: Generic specification - Basic optical cable test procedures - Electrical test methods	
prEN 60794-1-31	Optical fibre cables - Part 1-31: Sectional specification for cable element - Optical fibre ribbon	Under development
EN 60794-2-10:2011	Optical fibre cables - Part 2-10: Indoor optical fibre cables - Family specification for simplex and duplex cables	
EN 60794-2-20:2014	Optical fibre cables - Part 2-20: Indoor cables - Family specification for multi-fibre optical cables	
EN 60794-2-21:2012	Optical fibre cables - Part 2-21: Indoor optical fibre cables - Detailed specification for multi-fibre optical distribution cables for use in premises cabling	Revision: prEN 60794-2-21
EN 60794-2-22:2017	Optical fibre cables - Part 2-22: Indoor cables - Detail specification for multi-simplex breakout optical cables to be terminated with connectors	
EN 60794-2-30:2008	Optical fibre cables - Part 2-30: Indoor optical cables - Family specification for optical fibre ribbon cables for use in terminated cable assemblies	Revision: FprEN 60794-2-30
EN 60794-2-31:2013	Optical fibre cables - Part 2-31: Indoor cables - Detailed specification for optical fibre ribbon cables for use in premises cabling	Revision: prEN 60794-2-31
EN 60794-2-40:2008	Optical fibre cables - Part 2-40: Indoor optical fibre cables - Family specification for A4 fibre cables	
EN 60794-2-	Optical fibre cables - Part 2-41: Indoor cables - Product	

41:2008	specification for simplex and duplex buffered A4 fibres	
EN 60794-2-42:2008	Optical fibre cables - Part 2-42: Indoor optical fibre cables - Product specification for simplex and duplex cables with A4 fibres	
EN 60794-2-50:2008	Optical fibre cables - Part 2-50: Indoor optical fibre cables - Family specification for simplex and duplex cables for use in terminated cable assemblies	Revision: prEN 60794-2-50
EN 60794-2-51:2014	Optical fibre cables - Part 2-51: Indoor cables - Detail specification for simplex and duplex cables for use in cords for controlled environment	
EN 60794-2:2003	Optical fibre cables - Part 2: Indoor cables - Sectional specification	
EN 60794-2:2017	Optical fibre cables - Part 2: Indoor cables - Sectional specification	
EN 60794-5:2007	Optical fibre cables - Part 5: Sectional specification - Microduct cabling for installation by blowing	
EN 60794-5:2016	Optical fibre cables - Part 5: Sectional specification - Microduct cabling for installation by blowing	

CLC/TC 106X Electromagnetic fields in human environment

Scope:

TC 106X deals with various aspects of the exposure of people to electromagnetic fields from 0 Hz to 300 GHz

Table 16. List of CLC/TC 106X standards and standards under development

Standard reference	Title	Status
EN 50413:2008	Basic standard on measurement and calculation procedures for human exposure to electric, magnetic and electromagnetic fields (0 Hz - 300 GHz)	Revision: prEN 50413
EN 50499:2008	Procedure for the assessment of the exposure of workers to electromagnetic fields	Revision: prEN 50499
EN 50663:2017	Generic standard for assessment of low power electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (10 MHz - 300 GHz)	
EN 50664:2017	Generic standard to demonstrate the compliance of equipment used by workers with limits on exposure to	

	electromagnetic fields (0 Hz - 300 GHz), when put into service or in situ	
EN 50665:2017	Generic standard for assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz - 300 GHz)	
EN 61786-1:2014	Measurement of DC magnetic, AC magnetic and AC electric fields from 1 Hz to 100 kHz with regard to exposure of human beings - Part 1: Requirements for measuring instruments	
EN 62110:2009	Electric and magnetic field levels generated by AC power systems - Measurement procedures with regard to public exposure	
EN 62226-1:2005	Exposure to electric or magnetic fields in the low and intermediate frequency range - Methods for calculating the current density and internal electric field induced in the human body - Part 1: General	
EN 62226-2-1:2005	Exposure to electric or magnetic fields in the low and intermediate frequency range - Methods for calculating the current density and internal electric field induced in the human body - Part 2-1: Exposure to magnetic fields - 2D models	
EN 62226-3-1:2007 + Amendment A1:2017	Exposure to electric or magnetic fields in the low and intermediate frequency range - Methods for calculating the current density and internal electric field induced in the human body - Part 3-1: Exposure to electric fields - Analytical and 2D numerical models	
EN 62311:2008	Assessment of electronic and electrical equipment related to human exposure restrictions for electromagnetic fields (0 Hz - 300 GHz)	Revision: prEN 62311
EN 62369-1:2009	Evaluation of human exposure to electromagnetic fields from short range devices (SRDs) in various applications over the frequency range 0 GHz to 300 GHz - Part 1: Fields produced by devices used for electronic article surveillance, radio frequency identification and similar systems	
EN 62479:2010	Assessment of the compliance of low power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz)	

ISO/TC 170 Surgical instruments

Scope:

Standardization in the field of surgical instruments such as forceps, scissors, scalpels and retractors.

Excluded :
specific instruments which are dealt with in ISO / TC 106 - Dentistry, and ISO / TC 150 - Implants for surgery.

Table 17. List of CLC/TC 170 standards and standards under development

Standard reference	Title	Status
ISO 7151:1988	Surgical instruments - Non-cutting, articulated instruments - General requirements and test methods	
ISO 7153-1:2016	Surgical instruments - Materials - Part 1: Metals	
ISO 7740:1985	Instruments for surgery - Scalpels with detachable blades - Fitting dimensions	
ISO 7741:1986	Instruments for surgery - Scissors and shears - General requirements and test methods	
ISO 13402:1995	Surgical and dental hand instruments - Determination of resistance against autoclaving, corrosion and thermal exposure	

ISO/TC 194 Biological and clinical evaluation of medical devices

Scope:

Standardization of the approach to biological and clinical evaluation of medical and dental materials and devices together with standardization of biological test methods applicable to those materials and devices as well as good clinical practice principles to clinical investigations in humans of those devices.

Table 18. List of ISO/TC 194 standards and standards under development

Standard reference	Title	Status
ISO 10993-1:2018	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	
ISO 10993-2:2006	Biological evaluation of medical devices - Part 2: Animal	

	welfare requirements	
ISO 10993-3:2014	Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	
ISO 10993-4:2017	Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood	
ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity	
ISO 10993-6:2016	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation	
ISO 10993-7:2008	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals	Under development amendment: ISO/CD Amd1
ISO 10993-9:2009	Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products	Revision: ISO/DIS 10993-9
ISO 10993-10:2010	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	Revision: ISO/AWI 10993-10
ISO 10993-11:2017	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	
ISO 10993-12:2012	Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	Revision: ISO/AWI 10993-12
ISO 10993-13:2010	Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices	
ISO 10993-14:2001	Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products from ceramics	
ISO 10993-15:2000	Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys	Revision: ISO/DIS 10993-15
ISO 10993-16:2017	Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables	
ISO 10993-17:2002	Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances	
ISO 10993-18:2005	Biological evaluation of medical devices - Part 18: Chemical	Revision:

	characterization of materials	ISO/CD 10993-18
ISO/TS 10993-19:2006	Biological evaluation of medical devices - Part 19: Physico-chemical, morphological and topographical characterization of materials	Revision: ISO/DTR 10993-19
ISO/TS 10993-20:2006	Biological evaluation of medical devices - Part 20: Principles and methods for immunotoxicology testing of medical devices	
ISO/TR 10993-22:2017	Biological evaluation of medical devices - Part 22: Guidance on nanomaterials	
ISO/TR 10993-33:2015	Biological evaluation of medical devices - Part 33: Guidance on tests to evaluate genotoxicity - Supplement to ISO 10993-3	Revision: ISO/WD 10993-23
ISO 14155:2011	Clinical investigation of medical devices for human subjects - Good clinical practice	
ISO/DIS 14155	Clinical investigation of medical devices for human subjects - Good clinical practice	Under development
ISO/TR 15499:2016	Biological evaluation of medical devices - Guidance on the conduct of biological evaluation within a risk management process	
ISO/DTR 21582	Pyrogenicity - Principle and method for pyrogen testing of medical devices	Under development
ISO/DTS 21726	Biological evaluation of medical devices - Application of the threshold of toxicological concern (TTC) for assessing biocompatibility of extractable substances from medical devices	Under development

ISO/TC 198 Sterilization of health-care products

Scope:

Standardization of processes and equipment for sterilization of health-care products.

Table 19. List of ISO/TC 198 standards and standards under development

Standard reference	Title	Status
ISO 11138-1:2017	Sterilization of health care products - Biological indicators - Part 1: General requirements	

ISO 11138-2:2017	Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes	
ISO 11138-3:2017	Sterilization of health care products - Biological indicators - Part 3: Biological indicators for moist heat sterilization processes	
ISO 11138-4:2017	Sterilization of health care products - Biological indicators - Part 4: Biological indicators for dry heat sterilization processes	
ISO 11138-5:2017	Sterilization of health care products - Biological indicators - Part 5: Biological indicators for low-temperature steam and formaldehyde sterilization processes	
ISO/AWI 11138-6	Sterilization of health care products - Biological indicators - Part 6: Biological indicators for hydrogen peroxide sterilization processes	Under development
ISO/DIS 11138-7	Sterilization of health care products - Biological indicators - Part 7: Guidance for the selection, use and interpretation of results	Under development
ISO/CD 11138-8	Sterilization of health care products - Biological indicators - Part 8: Method for validation of a reduced incubation time for a biological indicator	Under development
ISO 11139:2018	Sterilization of health care products - Vocabulary of terms used in sterilization and related equipment and process standards	
ISO/TS 11139:2006	Sterilization of health care products - Vocabulary	
ISO 11140-1:2014	Sterilization of health care products - Chemical indicators - Part 1: General requirements	
ISO 11140-3:2007	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 11140-4:2007	Sterilization of health care products - Chemical indicators - Part 4: Class 2 indicators as an alternative to the Bowie and Dick-type test for detection of steam penetration	
ISO 11140-5:2007	Sterilization of health care products - Chemical indicators - Part 5: Class 2 indicators for Bowie and Dick-type air removal tests	
ISO/CD 11140-6	Sterilization of health care products - Chemical indicators - Part 6: Class 2 indicators and process challenge devices for use in performance testing of steam sterilizers	Under development

ISO 11607-1:2006 + Amendment Amd1:2014	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	Revision: ISO/FDIS 11607-1
ISO 11607-2:2006 + Amendment Amd1:2014	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	Revision: ISO/FDIS 11607-2
ISO 14161:2009	Sterilization of health care products - Biological indicators - Guidance for the selection, use and interpretation of results	
ISO 15882:2008	Sterilization of health care products - Chemical indicators - Guidance for selection, use and interpretation of results	
ISO 15883-1:2006 + Amendment Amd1:2014	Washer-disinfectors - Part 1: General requirements, terms and definitions and tests	
ISO 15883-2:2006	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 15883-3:2006	Washer-disinfectors - Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers	
ISO 15883-4:2008	Washer-disinfectors - Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes	Revision: ISO/FDIS 15883-4
ISO/TS 15883-5:2005	Washer-disinfectors - Part 5: Test soils and methods for demonstrating cleaning efficacy	Revision: ISO/CD 15883-5
ISO 15883-6:2011	Washer-disinfectors - Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment	
ISO 15883-7:2016	Washer-disinfectors - Part 7: Requirements and tests for washer-disinfectors employing chemical disinfection for non-invasive, non-critical thermolabile medical devices and healthcare equipment	
ISO/TS 16775:2014	Packaging for terminally sterilized medical devices - Guidance on the application of ISO 11607-1 and ISO 11607-2	
ISO/TS 17665-3:2013	Sterilization of health care products - Moist heat - Part 3: Guidance on the designation of a medical device to a product family and processing category for steam sterilization	

ISO 18472:2018	Sterilization of health care products - Biological and chemical indicators - Test equipment	
ISO/DTS 19572	Sterilization of health care products - Guidance on the application of ISO14937 to the sterilization of medical devices using Ethylene Oxide in a flexible sterilization chamber	Under development
ISO/TS 19930:2017	Guidance on aspects of a risk-based approach to assuring sterility of terminally sterilized, single-use health care product that is unable to withstand processing to achieve maximally a sterility assurance level of 10-6	
ISO/CD 22913	Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 2: Medical devices not intended for direct patient contact	Under development

ISO/TC 210 Quality management and corresponding general aspects for medical devices

Scope:

Standardization of requirements and guidance in the field of quality management and corresponding general aspects for medical devices. Standards for small bore connectors.

Excluded:

- generic quality management standards dealt with by ISO / TC 176;
- quality management standards for pharmaceutical products;
- technical requirements for specific types of medical devices (Note: Small bore connectors are components of a range of medical devices but are not themselves medical devices).

Note: In order to promote global harmonization the technical committee may also develop standards on general aspects stemming from the application of quality principles to medical devices, where these are not covered by the scope of another technical committee.

Standardization of processes and equipment for sterilization of health care products.

Table 20. List of ISO/TC 210 standards and standards under development

Standard reference	Title	Status
ISO 15223-2:2010	Medical devices - Symbols to be used with medical device	

	labels, labelling, and information to be supplied - Part 2: Symbol development, selection and validation	
ISO 16142-1:2016	Medical devices - Recognized essential principles of safety and performance of medical devices - Part 1: General essential principles and additional specific essential principles for all non-IVD medical devices and guidance on the selection of standards	
ISO 16142-2:2017	Medical devices - Recognized essential principles of safety and performance of medical devices - Part 2: General essential principles and additional specific essential principles for all IVD medical devices and guidance on the selection of standards	
ISO/TS 19218-1:2011 + Amendment Amd1:2013	Medical devices - Hierarchical coding structure for adverse events - Part 1: Event-type codes	
ISO/TS 19218-2:2012	Medical devices - Hierarchical coding structure for adverse events - Part 2: Evaluation codes	
ISO/CD 20417	Medical Devices - Requirements for general information to be provided by the manufacturer	Under development
ISO/TR 24971:2013	Medical devices - Guidance on the application of ISO 14971	Revision: ISO/DTR 24971
IEC 62304:2006 + Amendment Amd1:2015	Medical device software - Software life cycle processes	
IEC 62366-1:2015	Medical devices - Part 1: Application of usability engineering to medical devices	Under development amendment: ISO/CD Amd1
IEC/TR 62366-2:2016	Medical devices - Part 2: Guidance on the application of usability engineering to medical devices	
IEC/TR 80002-1:2009	Medical device software - Part 1: Guidance on the application of ISO 14971 to medical device software	
ISO/TR 80002-2:2017	Medical device software - Part 2: Validation of software for medical device quality systems	
IEC/TR 80002-3:2014	Medical device software - Part 3: Process reference model of medical device software life cycle processes (IEC 62304)	

ISO/TC 215 Health informatics

Scope:

Standardization 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.

Table 21. List of ISO/TC 215 standards and standards under development

Standard reference	Title	Status
ISO 10159:2011	Health informatics - Messages and communication - Web access reference manifest	
ISO/TR 11487:2008	Health informatics - Clinical stakeholder participation in the work of ISO TC 215	
ISO/TR 11633-1:2009	Health informatics - Information security management for remote maintenance of medical devices and medical information systems - Part 1: Requirements and risk analysis	Revision: ISO/DTS 11633-1
ISO/TR 11633-2:2009	Health informatics - Information security management for remote maintenance of medical devices and medical information systems - Part 2: Implementation of an information security management system (ISMS)	
ISO/TR 11636:2009	Health Informatics - Dynamic on-demand virtual private network for health information infrastructure	
ISO/TR 12300:2014	Health informatics - Principles of mapping between terminological systems	
ISO/TR 12309:2009	Health informatics - Guidelines for terminology development organizations	
ISO/TR 12310:2015	Health informatics - Principles and guidelines for the measurement of conformance in the implementation of terminological systems	
ISO/DIS 12381	Health informatics - Explicit time-related expressions for healthcare-specific problems	Under development
ISO/TR 12773-1:2009	Business requirements for health summary records - Part 1: Requirements	
ISO/TR 12773-2:2009	Business requirements for health summary records - Part 2: Environmental scan	
ISO/TR 13054:2012	Knowledge management of health information standards	
ISO/TR 13128:2012	Health Informatics - Clinical document registry federation	
ISO/TS 13582:2015	Health informatics - Sharing of OID registry information	

ISO 13606-2:2008	Health informatics - Electronic health record communication - Part 2: Archetype interchange specification	Revision: ISO/DIS 13606-2
ISO 13606-3:2009	Health informatics - Electronic health record communication - Part 3: Reference archetypes and term lists	Revision: ISO/DIS 13606-3
ISO/TS 13606-4:2009	Health informatics - Electronic health record communication - Part 4: Security	Revision: ISO/DIS 13606-4
ISO/TS 13972:2015	Health informatics - Detailed clinical models, characteristics and processes	
ISO 14199:2015	Health informatics - Information models - Biomedical Research Integrated Domain Group (BRIDG) Model	Revision: ISO/CD 14199
ISO/TS 14265:2011	Health Informatics - Classification of purposes for processing personal health information	
ISO/TR 14292:2012	Health informatics - Personal health records - Definition, scope and context	
ISO/TS 14441:2013	Health informatics - Security and privacy requirements of EHR systems for use in conformity assessment	
ISO/HL7 16527:2016	Health informatics - HL7 Personal Health Record System Functional Model, Release 1 (PHRS FM)	
ISO/TS 16791:2014	Health informatics - Requirements for international machine-readable coding of medicinal product package identifiers	Revision: ISO/AWI TS 16791
ISO 17115:2007	Health informatics - Vocabulary of compositional terminological systems	Revision: ISO/AWI 17115
ISO 17117-1:2018	Health informatics - Terminological resources - Part 1: Characteristics	
ISO/TR 17119:2005	Health informatics - Health informatics profiling framework	
ISO/TS 17251:2016	Health informatics - Business requirements for a syntax to exchange structured dose information for medicinal products	
ISO 17432:2004	Health informatics - Messages and communication - Web access to DICOM persistent objects	
ISO/TS 17439:2014	Health informatics - Development of terms and definitions for health informatics glossaries	Revision: ISO/WD 17439
ISO/TR 17791:2013	Health informatics - Guidance on standards for enabling safety in health software	
ISO/TS 17975:2015	Health informatics - Principles and data requirements for	

	consent in the Collection, Use or Disclosure of personal health information	
ISO 18232:2006	Health Informatics - Messages and communication - Format of length limited globally unique string identifiers	
ISO/TR 18307:2001	Health informatics - Interoperability and compatibility in messaging and communication standards - Key characteristics	
ISO 18308:2011	Health informatics - Requirements for an electronic health record architecture	
ISO/TS 18530:2014	Health Informatics - Automatic identification and data capture marking and labelling - Subject of care and individual provider identification	
ISO/TR 18638:2017	Health informatics - Guidance on health information privacy education in healthcare organizations	
ISO/TS 18864:2017	Health informatics - Quality metrics for detailed clinical models	
ISO/TR 19231:2014	Health informatics - Survey of mHealth projects in low and middle income countries (LMIC)	
ISO/TR 19669:2017	Health informatics - Re-usable component strategy for use case development	
ISO/PRF TR 20055	Health informatics - Person-owned document repository for PHR applications and health information exchange	Under development
ISO/TS 20405:2018	Health informatics - Framework of event data and reporting definitions for the safety of health software	
ISO/TR 20514:2005	Health informatics - Electronic health record - Definition, scope and context	
ISO/AWI TR 20841	Health informatics-Transnational Health Record	Under development
ISO/TS 21089:2018	Health informatics - Trusted end-to-end information flows	Under development
ISO/AWI TR 21332	Health informatics - Cloud computing considerations for health information systems security and privacy	Under development
ISO/AWI 21393	Health informatics - Omics Markup Language (OML)	Under development
ISO/AWI TS 21526	Health informatics - Metadata repository requirements (MetaRep)	Under development
ISO/TS 21547:2010	Health informatics - Security requirements for archiving of electronic health records – Principles	
ISO/TR 21548:2010	Health informatics - Security requirements for archiving of	

	electronic health records – Guidelines	
ISO/DTS 21564	Health Informatics - Terminology resource map quality measures (MapQual)	Under development
ISO 21667:2010	Health informatics - Health indicators conceptual framework	Revision: ISO/WD 21667
ISO/HL7 21731:2014	Health informatics - HL7 version 3 - Reference information model - Release 4	
ISO/WD 21667	Health informatics - Health indicators framework	Under development
ISO/DTR 21835	Health informatics - Health-related data which a person generates daily	Under development
ISO/AWI 21860	Health Informatics - Reference Standards Portfolio for Clinical Imaging (RSP-CI)	Under development
ISO/TR 22221:2006	Health informatics - Good principles and practices for a clinical data warehouse	
ISO/AWI TR 22272	Health informatics - Methodology for analysis of business and information needs of health enterprises to support standards based architectures	Under development
ISO/DTS 22287	Health informatics - Workforce roles and capabilities for terminology and terminology services (TermS)	Under development
ISO/AWI TS 22691	Health informatics - Token-based health information sharing	Under development
ISO/AWI 22697	Health informatics - Application of privacy management to personal health information	Under development
ISO 22857:2013	Health informatics - Guidelines on data protection to facilitate trans-border flows of personal health data	
ISO/AWI TS 23261	Requirements for accessing digital medicinal products information by using the existing data carrier	Under development
ISO 25237:2017	Health informatics – Pseudonymization	
ISO/TS 25238:2007	Health informatics - Classification of safety risks from health software	
ISO 25720:2009	Health informatics - Genomic Sequence Variation Markup Language (GSVML)	
ISO/AWI 25720	Health informatics - Genomic Sequence Variation Markup Language (GSVML)	Under development
ISO/TS 27527:2010	Health informatics - Provider identification	

ISO/TS 27790:2009	Health informatics - Document registry framework	
ISO/TR 27809:2007	Health informatics - Measures for ensuring patient safety of health software	
ISO/HL7 27931:2009	Data Exchange Standards - Health Level Seven Version 2.5 - An application protocol for electronic data exchange in healthcare environments	
ISO/HL7 27932:2009	Data Exchange Standards - HL7 Clinical Document Architecture, Release 2	
ISO/HL7 27951:2009	Health informatics - Common terminology services, release 1	
ISO/TR 28380-1:2014	Health informatics - IHE global standards adoption - Part 1: Process	
ISO/TR 28380-2:2014	Health informatics - IHE global standards adoption - Part 2: Integration and content profiles	
ISO/TR 28380-3:2014	Health informatics - IHE global standards adoption - Part 3: Deployment	
ISO/TS 29585:2010	Health informatics - Deployment of a clinical data warehouse	
ISO/DIS 62304	Health software - Software life cycle processes	Under development
IEC 80001-1:2010	Application of risk management for IT-networks incorporating medical devices - Part 1: Roles, responsibilities and activities	Revision: ISO/AWI 81001-1
IEC/TR 80001-2-8:2016	Application of risk management for IT-networks incorporating medical devices - Part 2-8: Application guidance - Guidance on standards for establishing the security capabilities identified in IEC 80001-2-2	
IEC/TR 80001-2-1:2012	Application of risk management for IT-networks incorporating medical devices - Part 2-1: Step by Step Risk Management of Medical IT-Networks; Practical Applications and Examples	
IEC/TR 80001-2-2:2012	Application of risk management for IT-networks incorporating medical devices - Part 2-2: Guidance for the communication of medical device security needs, risks and controls	
IEC/TR 80001-2-3:2012	Application of risk management for IT-networks incorporating medical devices - Part 2-3: Guidance for wireless networks	

IEC/TR 80001-2-4:2012	Application of risk management for IT-networks incorporating medical devices - Part 2-4: General implementation guidance for Healthcare Delivery Organizations	
IEC/TR 80001-2-5:2014	Application of risk management for IT-networks incorporating medical devices - Part 2-5: Application guidance - Guidance for distributed alarm systems	
ISO/TR 80001-2-6:2014	Application of risk management for IT-networks incorporating medical devices - Part 2-6: Application guidance - Guidance for responsibility agreements	
ISO/TR 80001-2-7:2015	Application of risk management for IT-networks incorporating medical devices - Application guidance - Part 2-7: Guidance for healthcare delivery organizations (HDOs) on how to self-assess	
IEC/TR 80001-2-9:2017	Application of risk management for IT-networks incorporating medical devices - Part 2-9: Application guidance - Guidance for use of security assurance cases to demonstrate confidence in IEC/TR 80001-2-2 security capabilities	
IEC 82304-1:2016	Health software - Part 1: General requirements for product safety	

ISO/TC 262 Risk management

Scope:

Standardization in the field of risk management

Table 22. List of ISO/TC 262 standards and standards under development

Standard reference	Title	Status
ISO 31000:2018	Risk management - Guidelines	
ISO/TR 31004:2013	Risk management - Guidance for the implementation of ISO 31000	
IEC 31010:2009	Risk management - Risk assessment techniques	Revision: ISO/DIS 31010
ISO/WD 31022	Risk management - Guidelines for the management of legal risk	Under development

ISO/TC 276 Biotechnology

Scope:

Standardization in the field of biotechnology processes that includes the following topics:

- Terms and definitions;
- biobanks and bioresources;
- analytical methods;
- bioprocessing;
- data processing including annotation, analysis, validation, comparability and integration; metrology.

ISO/TC 276 Biotechnology will work closely with related committees in order to identify standardization needs and gaps, and collaborate with other organisations to avoid duplications and overlapping standardization activities.

The committee will not pursue subjects within the scope of other TCs including but not limited to ISO/TC 212 and ISO/TC 34/SC 16.

Table 23. List of ISO/TC 276 standards and standards under development

Standard reference	Title	Status
ISO/DTR 20386	Inventory of biotechnology-related terms	Under development
ISO/FDIS 20387	Biotechnology - Biobanking - General requirements for biobanking	Under development
ISO/AWI TS 20388	Biotechnology - Biobanking - The Collection, processing, storage and transportation criteria for animal genetic resources	Under development
ISO/AWI 21899	Biotechnology - Biobanking - General requirements for the validation and verification of processing methods Project in biobanks	Under development
ISO/AWI 21973	Biotechnology - General requirements to establish specification of cell transportation	Under development
ISO/AWI 22758	Biotechnology - Biobanking - Implementation guide for ISO 20387	Under development

IEC/TC 62 Electrical equipment in medical practice

Scope:

To prepare international standards and other publications concerning electrical equipment, electrical systems and software used in healthcare and their effects on patients, operators, other persons and the environment.

NOTE: This scope includes items that are also within the scopes of other committees and will be addressed through cooperation. Attention will focus on safety and performance (e.g. radiation protection, data security, data integrity, data privacy and environmental aspects) and will contribute to regulatory frameworks. Healthcare includes medical practice as well as emergency medical services, homecare, and support of persons with disabilities in their daily lives (i.e. Ambient Assisted Living).

Table 24. List of IEC/TC 62 standards and standards under development

Standard reference	Title	Status
IEC/TR 60601-4-1:2018	Medical electrical equipment - Part 4-1: Guidance and interpretation - Medical electrical equipment and medical electrical systems employing a degree of autonomy	
IEC/TR 60601-4-2:2016	Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems	
IEC/TR 60601-4-3:2015	Medical electrical equipment - Part 4-3: Guidance and interpretation - Considerations of unaddressed safety aspects in the third edition of IEC 60601-1 and proposals for new requirements	Revision: IEC/TR 60601-4-3
IEC/TR 60601-4-4:2017	Medical electrical equipment - Part 4-4: Guidance and interpretation - Guidance for writers of particular standards when creating alarm system-related requirements	
IEC/TR 60513:1994	Fundamental aspects of safety standards for medical electrical equipment	
IEC/TR 61258:2008	Guidelines for the development and use of medical electrical equipment educational materials	
IEC/TR 61289:2011	High frequency surgical equipment and high frequency surgical accessories - Operation and maintenance	Revision: IEC/TR CD 61289
IEC/TR 62296:2009	Considerations of unaddressed safety aspects in the second edition of IEC 60601-1 and proposals for new requirements	

IEC/TR 62348:2012	Assessment of the impact of the most significant changes in Amendment 1 to IEC 60601-1:2005 and mapping of the clauses of IEC 60601-1:2005 to the previous edition	
IEC/TR 62354:2014	General testing procedures for medical electrical equipment	
ISO/TR 62366-2:2016	Medical devices - Part 2: Guidance on the application of usability engineering to medical devices	
IEC 62563-1:2009 + Amendment AMD1:2016	Medical electrical equipment - Medical image display systems - Part1: Evaluation methods	
IEC/CD 62563-2	Medical electrical equipment - Medical image display systems - Acceptance and constancy tests	Under development
IEC/PAS 63077:2016	Good refurbishment practices for medical imaging equipment	Revision: IEC/CD 63077
IEC/CD 63120	Environmental conscious design of medical electrical equipment – Particular requirements for refurbishment of medical electrical equipment and systems, for re-use of parts, for a management of critical or hazardous substances contained in medical electrical equipment and systems and for a closed loop Business-to-Business take back system	Under development
IEC/TR 80002-1:2009	Medical device software - Part 1: Guidance on the application of ISO 14971 to medical device software	
IEC/TR 80002-3:2014	Medical device software - Part 3: Process reference model of medical device software life cycle processes (IEC 62304)	

IEC/TC 86A Fibres and cables

Scope:

To prepare international standards for optical fibres and optical cables embracing all types of communications applications. This activity covers terminology, generic characteristics, test and measurement methods and specifications for all types of single-mode and multimode optical fibres and all types of optical fibre indoor and outdoor cables to ensure reliable system performance and operation.

Table 25. List of IEC/TC 86A standards and standards under development

Standard reference	Title	Status
PNW 86A-1835	Optical Fibre Cables Part 6: Indoor-Outdoor cables - Sectional specification for Indoor-Outdoor cables	Under development
PNW 86A-1836	Optical Fibre Cables Part 6-10: Indoor-Outdoor cables -	Under

	Family specification for a Universal Indoor-Outdoor cable	development
PNW 86A-1837	Optical Fibre Cables Part 6-20: Indoor-Outdoor cables - Family specification for Flame Retardant Outdoor cables	Under development
PNW 86A-1838	Optical Fibre Cables Part 6-30: Indoor-Outdoor cables - Family specification for Weatherized Indoor cables	Under development
IEC/ACD 60794-1-202	Optical fibre cables –Part 1-202: Generic specification–Basic optical cable test procedures–Material compatibility test	Under development
IEC/CD 60794-1-215	Optical Fibre Cables – Part 1-215: Generic specification–Basic optical cable test procedures–Environmental test methods – Cable external freezing test, Method F15	Under development
IEC 60794-2-11:2012	Optical fibre cables - Part 2-11: Indoor optical fibre cables - Detailed specification for simplex and duplex cables for use in premises cabling	
IEC/APUB 60794-2-30	Optical fibre cables - Part 2-30: Indoor optical fibre cables - Family specification for optical fibre ribbon cables for use in terminated cable assemblies	Under development
IEC/ACD 60794-2-50	Optical fibre cables - Part 2-50: Indoor optical fibre cables - Family specification for simplex and duplex cables for use in terminated cable assemblies	Under development
IEC 60794-5-10:2014	Optical fibre cables - Part 5-10: Family specification - Outdoor microduct optical fibre cables, microducts and protected microducts for installation by blowing	
IEC 60794-5-20:2014	Optical fibre cables - Part 5-20: Family specification - Outdoor microduct fibre units, microducts and protected microducts for installation by blowing	
IEC/TR 62000:2010	Guidance for combining different single-mode fibres types	
IEC/TS 62033:2000	Attenuation uniformity in optical fibres	
IEC/TR 62048:2014	Optical fibres - Reliability - Power law theory	
IEC/TR 62221:2012	Optical fibres - Measurement methods - Microbending sensitivity	
IEC/TR 62284:2003	Effective area measurements of single-mode optical fibres - Guidance	
IEC/TR 62285:2005	Application guide for non-linear coefficient measuring methods	
IEC/TR 62316:2017	Guidance for the interpretation of OTDR backscattering traces for single-mode fibres	
IEC/TR 62324:2007	Single-mode optical fibres - Raman gain efficiency measurement using continuous wave method - Guidance	
IEC/TR 62349:2014	Guidance of measurement methods and test procedures -	

	Basic tests for polarization-maintaining optical fibres	
IEC/TR 62362:2010	Selection of optical fibre cable specifications relative to mechanical, ingress, climatic or electromagnetic characteristics - Guidance	
IEC/TR 62469:2007	Guidance for residual stress measurement of optical fibre	
IEC/TR 62470:2011	Guidance on techniques for the measurement of the coefficient of friction (COF) between cables and ducts	
IEC/TR 62547:2013	Guidelines for the measurement of high-power damage sensitivity of single-mode fibre to bends - Guidance for interpretation of results	
IEC/TR 62690:2014	Hydrogen effects in optical fibre cables - Guidelines	
IEC/TR 62691:2016	Optical fibre cables - Guidelines to the installation of optical fibre cables	
IEC/TR 62901:2016	Guide for the selection of drop cables	
IEC/CDTR 63194	Colour coding of optical fibre cables - Guidelines	Under development

IEC/TC 106 Methods for the assessment of electric, magnetic and electromagnetic fields associated with human exposure

Scope:

To prepare international standards on measurement and calculation methods to assess human exposure to electric, magnetic and electromagnetic fields. The task includes:

- characterisation of the electromagnetic environments with regard to human exposure;
- measurement methods, instrumentation and procedures;
- calculation methods;
- assessment methods for the exposure produced by specific sources (in so far as this task is not carried out by specific product committees);
- basic standards for other sources;
- assessment of uncertainties.

It covers the whole frequency range from 0 Hz to 300 GHz. It applies to basic restrictions and reference levels.

Excluded are:

- the establishment of exposure limits (see AC/38/2009 of 2009-11-27);
- mitigation methods which have to be dealt with by the relevant product committees;
- electrical safety (however, the issue of contact current related to the indirect effect of human exposure to electromagnetic fields is included).

Table 26. List of IEC/TC 106 standards and standards under development

Standard reference	Title	Status
IEC 61786-2:2014	Measurement of DC magnetic, AC magnetic and AC electric fields from 1 Hz to 100 kHz with regard to exposure of human beings - Part 2: Basic standard for measurements	
IEC 62209-1:2016	Measurement procedure for the assessment of specific absorption rate of human exposure to radio frequency fields from hand-held and body-mounted wireless communication devices - Part 1: Devices used next to the ear (Frequency range of 300 MHz to 6 GHz)	
IEC 62209-2:2010	Human exposure to radio frequency fields from hand-held and body-mounted wireless communication devices - Human models, instrumentation, and procedures - Part 2: Procedure to determine the specific absorption rate (SAR) for wireless communication devices used in close proximity to the human body (frequency range of 30 MHz to 6 GHz)	Under development amendment: IEC/CDV AMD1
IEC/CDV 62209-3	Human exposure to radio frequency fields from hand-held and body-mounted wireless communication devices - Human models, instrumentation, and procedures - Part 3: Vector probe systems (Frequency range of 100 MHz to 6 GHz)	Under development
IEC/CD 63184	Basic standard for the assessment of the human exposure to electric and magnetic fields from wireless power transfer systems - models, instrumentation, numerical methods and procedures (Frequency range of 1 kHz to 10 MHz)	Under development
IEC/PAS 63083:2017	Specific absorption rate (SAR) measurement procedure for long term evolution (LTE) devices	
IEC/PAS 63151:2018	Measurement procedure for the assessment of specific absorption rate of human exposure to radio frequency fields from hand-held and body-mounted wireless communication devices - Vector measurement-based systems (Frequency range of 30 MHz to 6 GHz)	
IEC/TR 62630:2010	Guidance for evaluating exposure from multiple electromagnetic sources	
IEC/TR 62669:2011	Case studies supporting IEC 62232 - Determination of RF field strength and SAR in the vicinity of radiocommunication base stations for the purpose of evaluating human exposure	
IEC/TR 62905:2018	Exposure assessment methods for wireless power transfer systems	
IEC/TR 63167:2018	Assessment of contact current related to human exposure to electric, magnetic and electromagnetic fields	
IEC/TR 63170:2018	Measurement procedure for the evaluation of power density related to human exposure to radio frequency fields from	

	wireless communication devices operating between 6 GHz and 100 GHz Hz.	
IEC/TS CDV 62764-1	Measurement procedures of magnetic field levels generated by electronic and electrical equipment in the automotive environment with respect to human exposure	Under development
IEC/IEEE CDV 62209-1528	Human exposure to radio frequency fields from hand-held and body-mounted wireless communication devices - Human models, instrumentation, and procedures: Measurement procedure for the assessment of specific absorption rate of human exposure to radio frequency fields from hand-held and body-worn wireless communication devices (Frequency range of 4 MHz to 10 GHz)	Under development
IEC/IEEE 62704-1:2017	Determining the peak spatial-average specific absorption rate (SAR) in the human body from wireless communications devices, 30 MHz to 6 GHz - Part 1: General requirements for using the finite difference time-domain (FDTD) method for SAR calculations	
IEC/IEEE 62704-2:2017	Determining the peak spatial-average specific absorption rate (SAR) in the human body from wireless communications devices, 30 MHz to 6 GHz - Part 2: Specific requirements for finite difference time domain (FDTD) modelling of exposure from vehicle mounted antennas	
IEC/IEEE 62704-3:2017	Determining the peak spatial-average specific absorption rate (SAR) in the human body from wireless communications devices, 30 MHz to 6 GHz - Part 3: Specific requirements for using the finite difference time domain (FDTD) method for SAR calculations of mobile phones	
IEC/IEEE CDV 62704-4	Recommended practise for determining the Peak Spatial Average Specific Absorption Rate (SAR) in the human body from wireless communications devices, 30 MHz - 6 GHz: General requirements for using the Finite-Element Method (FEM) for SAR calcutaions and specific requirements for modelling vehicle-mounted antennas and personal wireless devices	Under development
IEC/IEEE CD 62704-5	Determining the power density of the electromagnetic field associated with human exposure to wireless devices operating in close proximity to the head and body using computational techniques, 6 GHz to 300 GHz	Under development
IEC/IEEE CD 63195	Measurement procedure for the assessment of power density of human exposure to radio frequency fields from wireless devices operating in close proximity to the head and body – Frequency range of 6 GHz to 300 GHz	Under development