EUROPEAN
COMMISSION

M/575

Brussels, 14.4.2021
C(2021) 2406 final

COMMISSION IMPLEMENTING DECISION

of 14.4.2021

on a standardisation request to the European Committee for Standardization and the European Committee for Electrotechnical Standardization as regards medical devices in support of Regulation (EU) 2017/745 of the European Parliament and of the Council and *in vitro* diagnostic medical devices in support of Regulation (EU) 2017/746 of the European Parliament and of the Council

(Only the English, French and German texts are authentic)

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on a standardisation request to the European Committee for Standardization and the European Committee for Electrotechnical Standardization as regards medical devices in support of Regulation (EU) 2017/745 of the European Parliament and of the Council and *in vitro* diagnostic medical devices in support of Regulation (EU) 2017/746 of the European Parliament and of the Council

(Only the English, French and German texts are authentic)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 1025/2012 of the European Parliament and of the Council of 25 October 2012 on European standardisation, amending Council Directives 89/686/EEC and 93/15/EEC and Directives 94/9/EC, 94/25/EC, 95/16/EC, 97/23/EC, 98/34/EC, 2004/22/EC, 2007/23/EC, 2009/23/EC and 2009/105/EC of the European Parliament and of the Council and repealing Council Decision 87/95/EEC and Decision No 1673/2006/EC of the European Parliament and of the Council[1], and in particular Article 10(1) thereof,

Whereas:

(1) Regulation (EU) 2017/745 of the European Parliament and of the Council[2] lays down safety and performance requirements for medical devices for human use and system and process requirements for economic operators and sponsors of clinical investigations, in order to ensure a high level of protection of health and safety for patients and users and the smooth functioning of the internal market. Regulation (EU) 2017/746 of the European Parliament and of the Council[3] lays down such requirements for in vitro diagnostic medical devices for human use.

(2) In accordance with Article 8(1) of Regulation (EU) 2017/745 and Article 8(1) of Regulation (EU) 2017/746, devices and economic operators or sponsors that are in conformity with the relevant harmonised standards or the relevant parts thereof, the references of which have been published in the Official Journal of the European Union, are to be presumed to be in conformity with the requirements of Regulations (EU) 2017/745 or (EU) 2017/746 covered by those standards or parts thereof.

(3) Harmonised standards help ensuring a high level of protection of the health and safety for patients and users throughout the Union and thus contribute to the free movement of devices in the Union. Given that such standards are technology-neutral and

[1] OJ L 316, 14.11.2012, p. 12.

[2] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 5.5.2017, p. 1).

[3] Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 5.5.2017, p. 176).

performance-based, they also contribute to ensuring equal conditions of competition among economic operators dealing with devices, in particular small and medium-sized enterprises that are active in this sector. Indirectly, those standards also contribute to lower sales costs, benefitting patients and users in particular.

(4) Regulation (EU) 2017/745 replacing Council Directive 90/385/EEC[4] and Council Directive 93/42/EEC[5], and Regulation (EU) 2017/746 replacing Directive 98/79/EC of the European Parliament and of the Council[6] modify, among others, the requirements regarding design and manufacture of devices, labelling and instructions for use of such devices, and clinical investigation and performance studies concerning such devices. Those Regulations also modify the rules on the quality management system and set out detailed principles for the risk management requiring reduction of risks as far as possible without adversely affecting the benefit-risk ratio.

(5) Several harmonised standards have been drafted in support of Directives 90/385/EEC, 93/42/EEC and 98/79/EC on the basis of standardisation mandates issued by the Commission. Those harmonised standards need to be revised to take into account the requirements set out in Regulations (EU) 2017/745 and (EU) 2017/746.

(6) Standards developed at international level by the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC) on the basis of the Vienna agreement[7] and the Frankfurt agreement[8] need to be adopted as harmonised standards by the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (Cenelec) after adapting them to the Union legal framework.

(7) It is also necessary to draft new harmonised standards in relation to the requirements set out in Regulations (EU) 2017/745 and (EU) 2017/746.

(8) The intention to request a review or an update of the existing harmonised standards and drafting of new harmonised standards in support of Regulations (EU) 2017/745 and (EU) 2017/746 is stated in point 18 of the Commission Staff Working Document on the implementation of the actions foreseen in the annual Union work programme for European standardisation for 2018[9] accompanying that programme[10].

(9) CEN and Cenelec have indicated that the work covered by the request falls within their area of competence.

(10) It is therefore appropriate to request CEN and Cenelec to revise the existing harmonised standards and to draft new harmonised standards in support of Regulations (EU) 2017/745 and (EU) 2017/746.

(11) The harmonised standards should include detailed technical specifications in relation to the requirements set out in Regulations (EU) 2017/745 and (EU) 2017/746, especially with respect to the design and manufacture of devices, risk management and the obligations on economic operators and sponsors, including those relating to quality

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4 Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17).

5 Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1).

6 Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices (OJ L 331, 7.12.1998, p. 1).

7 Agreement on technical co-operation between ISO and CEN (Version 3.3 of 20 September 2001).

8 IEC-CENELEC Agreement on common planning of new work and parallel voting (Edition 3 of October 2016).

9 SWD(2017) 284 final of 25 August 2017.

10 COM(2017) 453 final of 25 August 2017.

management systems, risk management, clinical investigations and performance studies, and clinical evaluation and clinical evidence. They should also indicate clearly the correspondence between the technical specifications and the requirements they aim to cover.

(12) In accordance with point 1 of Chapter I of Annex I to Regulation (EU) 2017/745 and point 1 of Chapter I of Annex I to Regulation (EU) 2017/746, devices are to be safe and effective and not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art. Technical specifications included in the harmonised standards should support the attainment of those objectives.

(13) In accordance with point (h) of section 23.1 of Chapter III of Annex I to Regulation (EU) 2017/745 and point (h) of section 20.1 of Chapter III of Annex I to Regulation (EU) 2017/746, the information supplied by the manufacturer of the device is to take the form of internationally recognised symbols conforming to the harmonised standards or common specifications. Moreover, in accordance with Article 10(11) of Regulation (EU) 2017/745 and Article 10(10) of Regulation (EU) 2017/746, the use of symbols in device information is to take into account the intended users or patients. In order to ensure that users, patients and economic operators understand correctly the meaning of any such symbols, a description of the meaning of the symbols should be publicly available, without prejudice to any copyright to the relevant harmonised standard or its parts.

(14) Information as to which legal requirements are covered or partially covered by a harmonised standard is necessary when assessing, in accordance with Article 10(5) of Regulation (EU) No 1025/2012, the compliance of the documents drafted by CEN and Cenelec. Such information is also necessary before publication of references of harmonised standards in the Official Journal of the European Union in accordance with Article 10(6) of Regulation (EU) No 1025/2012. In each harmonised standard, CEN and Cenelec should therefore specify the extent to which the technical specifications included in the harmonised standard aim to cover one or several requirements set out in Regulation (EU) 2017/745 or Regulation (EU) 2017/746.

(15) The European standardisation organisations have agreed to follow the Guidelines for the execution of standardisation requests[11].

(16) In order to ensure transparency and facilitate the execution of the requested standardisation activities, CEN and Cenelec should prepare a work programme and submit it to the Commission.

(17) In order to enable the Commission to better monitor the requested standardisation work, CEN and Cenelec should provide the Commission with access to an overall project plan containing detailed information on the execution of the standardisation request and should report regularly on the execution of that request.

(18) Experience shows that during execution of the standardisation request, it may be necessary to adjust the scope of the request or the deadlines set therein. CEN and Cenelec should therefore promptly report to the Commission if they consider that more time is required to draft the standards than initially foreseen or that it is

[11] SWD(2015) 205 final of 27 October 2015.

appropriate to adapt the scope of the request in order to allow the Commission to take appropriate action.

(19) In accordance with Article 10(3) of Regulation (EU) No 1025/2012, each standardisation request is subject to acceptance by the relevant European standardisation organisation. It is therefore necessary to provide for rules on the validity of this request if it is not accepted by CEN or Cenelec.

(20) In order to ensure legal certainty as to the validity of the request after its execution, it is appropriate to provide for a date of expiry of this Decision.

(21) Given that Directives 90/385/EEC and 93/42/EEC are repealed as of 26 May 2021 and Directive 98/79/EC is repealed as of 26 May 2022, it is appropriate to provide for the end of validity of standardisation mandates that have been issued by the Commission for drafting harmonised standards in support of those Directives.

(22) Given that a standardisation request as regards medical devices in support of Regulations (EU) 2017/745 and (EU) 2017/746 set out in Implementing Decision C(2020) 2532[12] was not accepted by CEN and Cenelec, it is appropriate to repeal that Decision.

(23) The European standardisation organisations, the European stakeholders' organisations receiving Union financing, and the Medical Device Coordination Group established by Article 103 of Regulation (EU) 2017/745 have been consulted.

(24) Article 5(1) of Implementing Decision C(2020) 2532 contains an error by providing for expiry of standardisation mandate 'M/321 of 13 June 2002' on 26 May 2020. Mandate 'M/321 of 13 June 2002' is also referred to in Article 5(2) of Implementing Decision C(2020) 2532 providing for its expiry on 26 May 2022, which is the correct expiry date.

(25) The measures provided for in this Decision are in accordance with the opinion of the Committee established by Article 22 of Regulation (EU) No 1025/2012,

HAS ADOPTED THIS DECISION:

Article 1

Requested standardisation activities

1. The European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (Cenelec) are requested to revise the existing harmonised standards listed in Table 1 of Annex I to this Decision and to draft the new harmonised standards listed in Table 2 of that Annex in support of Regulation (EU) 2017/745 for medical devices by the deadlines set in that Annex.

2. CEN and Cenelec are requested to revise the existing standards listed in Table 1 of Annex II to this Decision and to draft the new harmonised standards listed in Table 2 of that Annex in support of Regulation (EU) 2017/746 for *in vitro* diagnostic medical devices by the deadlines set in that Annex.

3. The standards referred to in paragraphs 1 and 2 shall meet the requirements set out in Annex III.

[12] Commission Implementing Decision C(2020) 2532 of 15 May 2020 on a standardisation request to the European Committee for Standardization and the European Committee for Electrotechnical Standardization as regards medical devices in support of Regulation (EU) 2017/745 of the European Parliament and of the Council and *in vitro* diagnostic medical devices in support of Regulation (EU) 2017/746 of the European Parliament and of the Council.

4. CEN and Cenelec shall provide the Commission with the titles of the requested standards in all official languages of the Union.

Article 2

Work programme

1. CEN and Cenelec shall prepare a joint work programme indicating all the standards listed in Annexes I and II, the responsible technical bodies and a timetable for the execution of the requested standardisation activities in line with the deadlines set out in those Annexes.

2. CEN and Cenelec shall submit the joint work programme to the Commission by 28 May 2021. CEN and Cenelec shall inform the Commission of any amendments to the joint work programme.

3. CEN and Cenelec shall provide the Commission with access to an overall project plan.

Article 3

Reporting

1. CEN and Cenelec shall report annually to the Commission on the execution of the standardisation request referred to in Article 1, indicating the progress made in implementation of the work programme referred to in Article 2.

2. CEN and Cenelec shall submit the first joint annual report to the Commission by 16 April 2022. Subsequent joint annual reports shall be submitted to the Commission by 31 October each year.

3. CEN and Cenelec shall provide the Commission with the joint final report by 30 June 2024.

4. CEN and Cenelec shall promptly report to the Commission any major concerns relating to the scope of the standardisation request referred to in Article 1 or the deadlines set in Annexes I and II.

Article 4

Validity of the standardisation request

If CEN or Cenelec do not accept the standardisation request referred to in Article 1 within a month of receiving it, the request may not constitute a basis for the standardisation activities referred to in that Article.

This Decision shall expire on 31 December 2024.

Article 5

Expiry of existing standardisation mandates and repeal of Implementing Decision C(2020) 2532

1. The following standardisation mandates shall expire on 26 May 2022:

   (a) M/252 of 12 September 1997;

   (b) M/321 of 13 June 2002;

   (c) M/384 of 6 April 2006.

2. Implementing Decision C(2020) 2532 is repealed.

Article 6

Addressees

This Decision is addressed to the European Committee for Standardization and the European Committee for Electrotechnical Standardization.

Done at Brussels, 14.4.2021

For the Commission
Stella KYRIAKIDES
Member of the Commission

CERTIFIED COPY
For the Secretary-General

Martine DEPREZ
Director
Decision-making & Collegiality
EUROPEAN COMMISSION

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ANNEXES 1 to 3

ANNEXES

to the

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on a standardisation request to the European Committee for Standardization and the European Committee for Electrotechnical Standardization as regards medical devices in support of Regulation (EU) 2017/745 of the European Parliament and of the Council and in vitro diagnostic medical devices in support of Regulation (EU) 2017/746 of the European Parliament and of the Council

ANNEX I

List of existing standards to be revised and list of new standards to be drafted as referred to in Article 1(1)

Table 1: List of existing harmonised standards to be revised and deadlines for the adoption of the revised harmonised standards

Reference information		Deadline for the adoption
1.	EN 285:2015 Sterilization - Steam sterilizers - Large sterilizers	27 May 2024
2.	EN 455-1:2020 Medical gloves for single use - Part 1: Requirements and testing for freedom from holes	27 May 2024
3.	EN 455-2:2015 Medical gloves for single use - Part 2: Requirements and testing for physical properties	27 May 2024
4.	EN 455-3:2015 Medical gloves for single use - Part 3: Requirements and testing for biological evaluation	27 May 2024
5.	EN 455-4:2009 Medical gloves for single use - Part 4: Requirements and testing for shelf life determination	27 May 2024
6.	EN 556-1:2001+AC:2006 Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices	27 May 2024
7.	EN 556-2:2015 Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 2: Requirements for aseptically processed medical devices	27 May 2024
8.	EN 1422:2014 Sterilizers for medical purposes - Ethylene oxide sterilizers - Requirements and test methods	27 May 2024

9.	EN 1865-1:2010+A1:2015 Patient handling equipment used in road ambulances - Part 1: General stretcher systems and patient handling equipment	27 May 2024
10.	EN 1865-2:2010+A1:2015 Patient handling equipment used in road ambulances - Part 2: Power assisted stretcher	27 May 2024
11.	EN 1865-3:2012+A1:2015 Patient handling equipment used in road ambulances - Part 3: Heavy duty stretcher	27 May 2024
12.	EN 1865-4:2012 Patient handling equipment used in road ambulances - Part 4: Foldable patient transfer chair	27 May 2024
13.	EN 1985:1998 Walking aids - General requirements and test methods	27 May 2024
14.	EN ISO 4074:2015 Natural rubber latex male condoms - Requirements and test methods	27 May 2024
15.	EN ISO 5359:2014+A1:2017 Anaesthetic and respiratory equipment - Low-pressure hose assemblies for use with medical gases	27 May 2024
16.	EN ISO 5840-1:2015 Cardiovascular implants - Cardiac valve prostheses - Part 1: General requirements	27 May 2024
17.	EN ISO 5840-2:2015 Cardiovascular implants - Cardiac valve prostheses - Part 2: Surgically implanted heart valve substitutes	27 May 2024
18.	EN ISO 5840-3:2013 Cardiovascular implants - Cardiac valve prostheses - Part 3: Heart valve substitutes implanted by transcatheter techniques	27 May 2024
19.	EN ISO 7010:2020+A1:2020	27 May 2024

	Graphical symbols - Safety colours and safety signs - Registered safety signs	
20.	EN ISO 7197:2009 Neurosurgical implants - Sterile, single-use hydrocephalus shunts and components	27 May 2024
21.	EN ISO 7396-1:2016+A1:2019 Medical gas pipeline systems - Part 1: Pipeline systems for compressed medical gases and vacuum	27 May 2024
22.	EN ISO 7396-2:2007 Medical gas pipeline systems - Part 2: Anaesthetic gas scavenging disposal systems	27 May 2024
23.	EN ISO 9713:2009 Neurosurgical implants - Self-closing intracranial aneurysm clips	27 May 2024
24.	EN ISO 10328:2016 Prosthetics - Structural testing of lower-limb prostheses - Requirements and test methods	27 May 2024
25.	EN ISO 10524-1:2019 Pressure regulators for use with medical gases - Part 1: Pressure regulators and pressure regulators with flow-metering devices	27 May 2024
26.	EN ISO 10524-2:2019 Pressure regulators for use with medical gases - Part 2: Manifold and line pressure regulators	27 May 2024
27.	EN ISO 10524-3:2019 Pressure regulators for use with medical gases - Part 3: Pressure regulators integrated with cylinder valves (VIPRs)	27 May 2024
28.	EN ISO 10535:2006 Hoists for the transfer of disabled persons - Requirements and test methods	27 May 2024
29.	EN ISO 10993-1:2020 Biological evaluation of medical devices - Part 1:	27 May 2024

	Evaluation and testing within a risk management process	
30.	EN ISO 10993-3:2014 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	27 May 2024
31.	EN ISO 10993-4:2017 Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood	27 May 2024
32.	EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for *in vitro* cytotoxicity	27 May 2024
33.	EN ISO 10993-6:2016 Biological evaluation of medical devices - Part 6: Tests for local effects after implantation	27 May 2024
34.	EN ISO 10993-7:2008+AC:2009 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals	27 May 2024
35.	EN ISO 10993-9:2009 Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products	27 May 2024
36.	EN ISO 10993-10:2013 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization	27 May 2024
37.	EN ISO 10993-11:2018 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	27 May 2024
38.	EN ISO 10993-12:2012 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	27 May 2024
39.	EN ISO 10993-13:2010 Biological evaluation of medical devices - Part 13:	27 May 2024

	Identification and quantification of degradation products from polymeric medical devices	
40.	EN ISO 10993-14:2009 Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products from ceramics	27 May 2024
41.	EN ISO 10993-15:2009 Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys	27 May 2024
42.	EN ISO 10993-16:2017 Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables	27 May 2024
43.	EN ISO 10993-17:2009 Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances	27 May 2024
44.	EN ISO 10993-18:2020 Biological evaluation of medical devices - Part 18: Chemical characterization of materials	27 May 2024
45.	EN ISO 11135:2014+A1:2019 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices	27 May 2024
46.	EN ISO 11137-1:2015+A2:2019 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	27 May 2024
47.	EN ISO 11137-2:2015 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose	27 May 2024

48.	EN ISO 11140-1:2014 Sterilization of health care products - Chemical indicators - Part 1: General requirements	27 May 2024
49.	EN ISO 11140-3:2009 Sterilization of health care products - Chemical indicators - Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test	27 May 2024
50.	EN 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	27 May 2024
51.	EN ISO 11197:2019 Medical supply units	27 May 2024
52.	EN ISO 11607-1:2020 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	27 May 2024
53.	EN ISO 11607-2:2020 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	27 May 2024
54.	EN ISO 11737-1:2018 Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products	27 May 2024
55.	EN ISO 11737-2:2020 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	27 May 2024
56.	EN ISO 11810:2015 Lasers and laser-related equipment - Test method and classification for the laser resistance of surgical drapes and/or patient protective covers - Primary ignition,	27 May 2024

	penetration, flame spread and secondary ignition	
57.	EN ISO 11990:2018 Lasers and laser-related equipment - Determination of laser resistance of tracheal tube shaft and tracheal cuffs	27 May 2024
58.	EN 12183:2014 Manual wheelchairs - Requirements and test methods	27 May 2024
59.	EN 12184:2014 Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods	27 May 2024
60.	EN ISO 12417-1:2015 Cardiovascular implants and extracorporeal systems - Vascular device-drug combination products - Part 1: General requirements	27 May 2024
61.	EN ISO 12870:2018 Ophthalmic optics - Spectacle frames - Requirements and test methods	27 May 2024
62.	EN 13060:2014+A1:2018 Small steam sterilizers	27 May 2024
63.	EN ISO 13408-1:2015 Aseptic processing of health care products - Part 1: General requirements	27 May 2024
64.	EN ISO 13408-2:2018 Aseptic processing of health care products - Part 2: Filtration	27 May 2024
65.	EN ISO 13408-3:2011 Aseptic processing of health care products - Part 3: Lyophilization	27 May 2024
66.	EN ISO 13408-4:2011 Aseptic processing of health care products - Part 4: Clean-in-place technologies	27 May 2024
67.	EN ISO 13408-5:2011	27 May 2024

	Aseptic processing of health care products - Part 5: Sterilization in place	
68.	EN ISO 13408-6:2011+A1:2013 Aseptic processing of health care products - Part 6: Isolator systems	27 May 2024
69.	EN ISO 13408-7:2015 Aseptic processing of health care products - Part 7: Alternative processes for medical devices and combination products	27 May 2024
70.	EN ISO 13485:2016+AC:2018 Medical devices - Quality management systems - Requirements for regulatory purposes	27 May 2024
71.	EN 13718-1:2014+A1:2020 Medical vehicles and their equipment - Air ambulances - Part 1: Requirements for medical devices used in air ambulances	27 May 2024
72.	EN 13795-1:2019 Surgical clothing and drapes - Requirements and test methods - Part 1: Surgical drapes and gowns	27 May 2024
73.	EN 13795-2:2019 Surgical clothing and drapes - Requirements and test methods - Part 2: Clean air suits	27 May 2024
74.	EN 13976-1:2018 Rescue systems - Transportation of incubators - Part 1: Interface requirements	27 May 2024
75.	EN 13976-2:2018 Rescue systems - Transportation of incubators - Part 2: System requirements	27 May 2024
76.	EN 14139:2010 Ophthalmic optics - Specifications for ready-to-wear spectacles	27 May 2024
77.	EN ISO 14155:2020 Clinical investigation of medical devices for human	27 May 2024

	subjects - Good clinical practice	
78.	EN ISO 14160:2011 Sterilization of health care products - Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives - Requirements for characterization, development, validation and routine control of a sterilization process for medical devices	27 May 2024
79.	EN 14180:2014 Sterilizers for medical purposes - Low temperature steam and formaldehyde sterilizers - Requirements and testing	27 May 2024
80.	EN ISO 14602:2011 Non-active surgical implants - Implants for osteosynthesis - Particular requirements	27 May 2024
81.	EN ISO 14607:2018 Non-active surgical implants - Mammary implants - Particular requirements	27 May 2024
82.	EN ISO 14630:2012 Non-active surgical implants - General requirements	27 May 2024
83.	EN 14683:2019+AC:2019 Medical face masks - Requirements and test methods	27 May 2024
84.	EN 14885:2018 Chemical disinfectants and antiseptics - Application of European standards for chemical disinfectants and antiseptics	27 May 2024
85.	EN ISO 14889:2013+A1:2017 Ophthalmic optics - Spectacle lenses - Fundamental requirements for uncut finished lenses	27 May 2024
86.	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	27 May 2024

87.	EN ISO 14971:2019 Medical devices - Application of risk management to medical devices	27 May 2024
88.	EN ISO 15001:2011 Anaesthetic and respiratory equipment - Compatibility with oxygen	27 May 2024
89.	EN ISO 15004-1:2020 Ophthalmic instruments - Fundamental requirements and test methods - Part 1: General requirements applicable to all ophthalmic instruments	27 May 2024
90.	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	27 May 2024
91.	EN ISO 15883-1:2009+A1:2014 Washer-disinfectors - Part 1: General requirements, terms and definitions and tests	27 May 2024
92.	EN ISO 15883-2:2009 Washer-disinfectors - Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc.	27 May 2024
93.	EN ISO 15883-3:2009 Washer-disinfectors - Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers	27 May 2024
94.	EN ISO 15883-4:2018 Washer-disinfectors - Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes	27 May 2024
95.	EN ISO 15883-6:2015 Washer-disinfectors - Part 6: Requirements and tests for washer-disinfectors employing thermal disinfection for non-invasive, non-critical medical devices and healthcare equipment	27 May 2024

96.	EN 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	27 May 2024
97.	EN ISO 16061:2015 Instrumentation for use in association with non-active surgical implants - General requirements	27 May 2024
98.	EN ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices	27 May 2024
99.	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	27 May 2024
100.	EN ISO 18562-1:2020 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process	27 May 2024
101.	EN ISO 18562-2:2020 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions of particulate matter	27 May 2024
102.	EN ISO 18562-3:2020 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic compounds (VOCs)	27 May 2024
103.	EN ISO 18562-4:2020 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 4: Tests for leachables in condensate	27 May 2024
104.	EN ISO 20857:2013 Sterilization of health care products - Dry heat -	27 May 2024

	Requirements for the development, validation and routine control of a sterilization process for medical devices	
105.	EN ISO 21534:2009 Non-active surgical implants - Joint replacement implants - Particular requirements	27 May 2024
106.	EN ISO 21535:2009+A1:2016 Non-active surgical implants - Joint replacement implants - Specific requirements for hip-joint replacement implants	27 May 2024
107.	EN ISO 21536:2009+A1:2014 Non-active surgical implants - Joint replacement implants - Specific requirements for knee-joint replacement implants	27 May 2024
108.	EN ISO 21987:2017 Ophthalmic optics - Mounted spectacle lenses	27 May 2024
109.	EN ISO 22442-1:2020 Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk management	27 May 2024
110.	EN ISO 22442-2:2020 Medical devices utilizing animal tissues and their derivatives - Part 2: Controls on sourcing, collection and handling	27 May 2024
111.	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	27 May 2024
112.	EN ISO 22523:2006 External limb prostheses and external orthoses - Requirements and test methods	27 May 2024
113.	EN ISO 22675:2016 Prosthetics - Testing of ankle-foot devices and foot units - Requirements and test methods	27 May 2024

114.	EN ISO 23908:2013 Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling	27 May 2024
115.	EN ISO 25424:2019 Sterilization of health care products - Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices	27 May 2024
116.	EN ISO 25539-1:2017 Cardiovascular implants - Endovascular devices - Part 1: Endovascular prostheses	27 May 2024
117.	EN ISO 25539-2:2020 Cardiovascular implants - Endovascular devices - Part 2: Vascular stents	27 May 2024
118.	EN ISO 25539-3:2011 Cardiovascular implants - Endovascular devices - Part 3: Vena cava filters	27 May 2024
119.	EN 50637:2017 Medical electrical equipment - Particular requirements for the basic safety and essential performance of medical beds for children	27 May 2024
120.	EN 60118-0:2015 Electroacoustics - Hearing aids - Part 0: Measurement of the performance characteristics of hearing aids	27 May 2024
121.	EN IEC 60118-13:2020 Electroacoustics - Hearing aids - Part 13: Requirements and methods of measurement for electromagnetic immunity to mobile digital wireless devices	27 May 2024
122.	EN 60601-1:2006+A1:2013+AC:2014+A12:2014 +A2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential	27 May 2024

	performance	
123.	EN 60601-1-2:2015+A1:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	27 May 2024
124.	EN 60601-1-3:2008+AC:2014+A11:2016+A1:2020 Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral standard: Radiation protection in diagnostic X-ray equipment	27 May 2024
125.	EN 60601-1-6:2010+A1:2015+A2:2020 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	27 May 2024
126.	EN 60601-1-8:2007+AC:2014+A11:2017+A2:2020 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	27 May 2024
127.	EN 60601-1-10:2008+A1:2015+A2:2020 Medical electrical equipment - Part 1-10: General requirements for basic safety and essential performance - Collateral standard: Requirements for the development of physiologic closed-loop controller	27 May 2024
128.	EN 60601-1-11:2015+A1:2020 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	27 May 2024
129.	EN 60601-1-12:2015+A1:2020 Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical	27 May 2024

	systems intended for use in the emergency medical services environment	
130.	EN 60601-2-1:2015 Medical electrical equipment - Part 2-1: Particular requirements for the basic safety and essential performance of electron accelerators in the range 1 MeV to 50 MeV	27 May 2024
131.	EN IEC 60601-2-2:2018 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	27 May 2024
132.	EN 60601-2-3:2015+A1:2016 Medical electrical equipment - Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment	27 May 2024
133.	EN 60601-2-4:2011+A1:2019 Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators	27 May 2024
134.	EN 60601-2-5:2015 Medical electrical equipment - Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment	27 May 2024
135.	EN 60601-2-6:2015+A1:2016 Medical electrical equipment - Part 2-6: Particular requirements for the basic safety and essential performance of microwave therapy equipment	27 May 2024
136.	EN 60601-2-8:2015+A1:2016 Medical electrical equipment - Part 2-8: Particular requirements for the basic safety and essential performance of therapeutic X-ray equipment operating in the range 10 kV to 1 MV	27 May 2024
137.	EN 60601-2-10:2015+A1:2016 Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential	27 May 2024

	performance of nerve and muscle stimulators	
138.	EN 60601-2-11:2015 Medical electrical equipment - Part 2-11: Particular requirements for the basic safety and essential performance of gamma beam therapy equipment	27 May 2024
139.	EN IEC 60601-2-16:2019 Medical electrical equipment - Part 2-16: Particular requirements for the basic safety and essential performance of haemodialysis, haemodiafiltration and haemofiltration equipment	27 May 2024
140.	EN 60601-2-17:2015 Medical electrical equipment - Part 2-17: Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy afterloading equipment	27 May 2024
141.	EN 60601-2-18:2015 Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment	27 May 2024
142.	EN IEC 60601-2-19:2020 Medical electrical equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators	27 May 2024
143.	EN IEC 60601-2-20:2020 Medical electrical equipment - Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators	27 May 2024
144.	EN IEC 60601-2-21:2020 Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers	27 May 2024
145.	EN 60601-2-23:2015 Medical electrical equipment - Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure	27 May 2024

	monitoring equipment	
146.	EN 60601-2-24:2015 Medical electrical equipment - Part 2-24: Particular requirements for the basic safety and essential performance of infusion pumps and controllers	27 May 2024
147.	EN 60601-2-25:2015 Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs	27 May 2024
148.	EN 60601-2-27:2014 Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment	27 May 2024
149.	EN IEC 60601-2-28:2019 Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis	27 May 2024
150.	EN 60601-2-29:2008+A11:2011 Medical electrical equipment - Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators	27 May 2024
151.	EN IEC 60601-2-31:2020 Medical electrical equipment - Part 2-31: Particular requirements for the basic safety and essential performance of external cardiac pacemakers with internal power source	27 May 2024
152.	EN 60601-2-33:2010+A11:2011+A1:2015+A2:2015+A12:2016 Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis	27 May 2024
153.	EN 60601-2-34:2014 Medical electrical equipment - Part 2-34: Particular	27 May 2024

	requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment	
154.	EN 60601-2-36:2015 Medical electrical equipment - Part 2-36: Particular requirements for the basic safety and essential performance of equipment for extracorporeally induced lithotripsy	27 May 2024
155.	EN 60601-2-37:2008+A11:2011+A1:2015 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment	27 May 2024
156.	EN IEC 60601-2-39:2019 Medical electrical equipment - Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment	27 May 2024
157.	EN 60601-2-40:2019 Medical electrical equipment - Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment	27 May 2024
158.	EN 60601-2-41:2009+A11:2011+A1:2015 Medical electrical equipment - Part 2-41: Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for diagnosis	27 May 2024
159.	EN 60601-2-43:2010+AC:2014+A1:2018+A2:2020 Medical electrical equipment - Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures	27 May 2024
160.	EN 60601-2-44:2009+A11:2011+A1:2012+A2:2016 Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography	27 May 2024

161.	EN 60601-2-45:2011+A1:2015 Medical electrical equipment - Part 2-45: Particular requirements for the basic safety and essential performance of mammographic X-ray equipment and mammographic stereotactic devices	27 May 2024
162.	EN IEC 60601-2-46:2019 Medical electrical equipment - Part 2-46: Particular requirements for the basic safety and essential performance of operating tables	27 May 2024
163.	EN 60601-2-47:2015 Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems	27 May 2024
164.	EN 60601-2-50:2009+A11:2011+A1:2016 Medical electrical equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment	27 May 2024
165.	EN 60601-2-52:2010+AC:2011+A1:2015 Medical electrical equipment - Part 2-52: Particular requirements for the basic safety and essential performance of medical beds	27 May 2024
166.	EN 60601-2-54:2009+A1:2015+A2:2019 Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy	27 May 2024
167.	EN 60601-2-62:2015 Medical electrical equipment - Part 2-62: Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment	27 May 2024
168.	EN 60601-2-63:2015+A1:2019 Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential performance of dental extra-oral X-ray equipment	27 May 2024

169.	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	27 May 2024
170.	EN 60601-2-65:2013+A1:2020 Medical electrical equipment - Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment	27 May 2024
171.	EN IEC 60601-2-66:2020 Medical electrical equipment - Part 2-66: Particular requirements for the basic safety and essential performance of hearing aids and hearing aid systems	27 May 2024
172.	EN 60601-2-68:2015 Medical electrical equipment - Part 2-68: Particular requirements for the basic safety and essential performance of X-ray-based image-guided radiotherapy equipment for use with electron accelerators, light ion beam therapy equipment and radionuclide beam therapy equipment	27 May 2024
173.	EN IEC 60601-2-75:2019 Medical electrical equipment - Part 2-75: Particular requirements for the basic safety and essential performance of photodynamic therapy and photodynamic diagnosis equipment	27 May 2024
174.	EN IEC 60601-2-76:2019 Medical electrical equipment - Part 2-76: Particular requirements for the basic safety and essential performance of low energy ionized gas haemostasis equipment	27 May 2024
175.	EN IEC 60601-2-83:2020 Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment	27 May 2024
176.	EN 61010-1:2010+A1:2019+AC:2019 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1:	27 May 2024

	General requirements	
177.	EN 61326-1:2013 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements	27 May 2024
178.	EN 62083:2009 Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems	27 May 2024
179.	EN 62304:2006+A1:2015 Medical device software - Software life-cycle processes	27 May 2024
180.	EN 62366-1:2015+AC:2015+AC:2016+A1:2020 Medical devices - Application of usability engineering to medical devices	27 May 2024
181.	EN 80001-1:2011 Safety, effectiveness and security in the implementation and use of connected medical devices or connected health software - Part 1: Application of risk management	27 May 2024
182.	EN ISO 80369-1:2018 Small-bore connectors for liquids and gases in healthcare applications - Part 1: General requirements	27 May 2024
183.	EN ISO 80369-3:2016 Small-bore connectors for liquids and gases in healthcare applications - Part 3: Connectors for enteral applications	27 May 2024
184.	EN ISO 80369-5:2016+AC:2017-02 Small-bore connectors for liquids and gases in healthcare applications - Part 5: Connectors for limb cuff inflation applications	27 May 2024
185.	EN ISO 80369-6:2016 Small bore connectors for liquids and gases in healthcare applications - Part 6: Connectors for neuraxial applications	27 May 2014

186.	EN ISO 80369-7:2017 Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications	27 May 2024
187.	EN ISO 80369-20:2015 Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods	27 May 2024
188.	EN ISO 80601-2-12:2020 Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators	27 May 2024
189.	EN ISO 80601-2-13:2011+A1:2019+A2:2019 Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation	27 May 2024
190.	EN IEC 80601-2-26:2020 Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs	27 May 2024
191.	EN IEC 80601-2-30:2019 Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers	27 May 2024
192.	EN IEC 80601-2-35:2019 Medical electrical equipment - Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use	27 May 2024
193.	EN IEC 80601-2-49:2019 Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment	27 May 2024

194.	EN ISO 80601-2-56:2017+A1:2020 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement	27 May 2024
195.	EN 80601-2-58:2015+A1:2019 Medical electrical equipment - Part 2-58: Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery	27 May 2024
196.	EN IEC 80601-2-59:2019 Medical electrical equipment - Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening	27 May 2024
197.	EN IEC 80601-2-60:2020 Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment	27 May 2024
198.	EN ISO 80601-2-69:2020 Medical electrical equipment - Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment	27 May 2024
199.	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	27 May 2024
200.	EN IEC 80601-2-78:2020 Medical electrical equipment - Part 2-78: Particular requirements for basic safety and essential performance of medical robots for rehabilitation, assessment, compensation or alleviation	27 May 2024
201.	EN 82304-1:2017 Health Software - Part 1: General requirements for product safety	27 May 2024

Table 2: List of new harmonised standards to be drafted and deadlines for their adoption

Reference information		Deadline for the adoption
1.	Medical gloves for single use - Part 5: Extractable chemical residues (prEN 455-5)	27 May 2024
2.	Radiation protection - Sealed radioactive sources - Leakage test methods (ISO 9978)	27 May 2024
3.	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23)	27 May 2024
4.	Active implantable medical devices - Electromagnetic compatibility - EMC test protocols for implantable cardiac pacemakers, implantable cardioverter defibrillators and cardiac resynchronization devices (ISO 14117)	27 May 2024
5.	Stainless steel steam boilers (prEN 14222)	27 May 2024
6.	Implants for surgery - Active implantable medical devices - Part 1: General requirements for safety, marking and for information to be provided by the manufacturer (ISO 14708-1)	27 May 2024
7.	Implants for surgery - Active implantable medical devices - Part 2: Cardiac pacemakers (ISO 14708-2)	27 May 2024
8.	Implants for surgery - Active implantable medical devices - Part 3: Implantable neurostimulators (ISO 14708-3)	27 May 2024
9.	Implants for surgery - Active implantable medical devices - Part 4: Implantable infusion pumps (ISO 14708-4)	27 May 2024
10.	Implants for surgery - Active implantable medical devices - Part 5: Circulatory support devices (ISO 14708-5)	27 May 2024
11.	Implants for surgery - Active implantable medical devices - Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators) (ISO 14708-6)	27 May 2024
12.	Implants for surgery - Active implantable medical devices - Part 7: Particular requirements for cochlear	27 May 2024

	and auditory brainstem implant systems (ISO 14708-7)	
13.	Washer-disinfectors - Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy (ISO 15883-5)	27 May 2024
14.	Sterilizers for medical purposes - Low temperature vapourized hydrogen peroxide sterilizers - Requirements and testing (prEN 17180)	27 May 2024
15.	Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices (ISO 17664-1)	27 May 2024
16.	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 (ISO 17664-2)	27 May 2024
17.	Assistive products for personal hygiene that support users - Requirements and test methods (ISO 17966)	27 May 2024
18.	Medical devices - Connectors for reservoir delivery systems for healthcare applications (ISO 18250)	27 May 2024
19.	Medical devices - Information to be provided by the manufacturer (ISO 20417)	27 May 2024
20.	Assistive products - General requirements and test methods (ISO 21856)	27 May 2024
21.	Lasers and laser-related equipment - Test methods for laser-induced damage threshold - Classification of medical beam delivery systems (ISO 22248)	27 May 2024
22.	Cardiac rhythm management devices - Symbols to be used with cardiac rhythm management device labels, and information to be supplied - General requirements (ISO 27185)	27 May 2024
23.	Active implantable medical devices - Four-pole connector system for implantable cardiac rhythm management devices - Dimensional and test requirements (ISO 27186)	27 May 2024
24.	Medical electrical equipment - Part 4-5: Guidance and interpretation - Safety related technical security specifications for medical devices (IEC TR 60601-4-5)	27 May 2024
25.	Medical electrical equipment - Part 2-86: Particular requirements for the basic safety and essential	27 May 2024

	performance of electrocardiographs, including diagnostic equipment, monitoring equipment, ambulatory equipment, electrodes, cables and leadwires (IEC 80601-2-86)	
26.	Medical electrical equipment - Part 2-89: Particular requirements for the basic safety and essential performance of medical beds for children (IEC 80601-2-89)	27 May 2024
27.	Health software and health IT systems safety, effectiveness and security - Part 5-1: Security - Activities in the product life cycle (IEC 81001-5-1)	27 May 2024

ANNEX II

List of existing standards to be revised and list of new standards to be drafted as referred to in Article 1(2)

Table 1: List of existing harmonised standards to be revised and deadlines for the adoption of the revised harmonised standards

Reference information		Deadline for the adoption
1.	EN 556-1:2001+AC:2006 Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices	27 May 2024
2.	EN 556-2:2015 Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 2: Requirements for aseptically processed medical devices	27 May 2024
3.	EN ISO 7010:2012 Graphical symbols - Safety colours and safety signs - Registered safety signs	27 May 2024
4.	EN ISO 11135:2014+A1:2019 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices	27 May 2024
5.	EN ISO 11137-1:2015+A2:2019 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	27 May 2024
6.	EN ISO 11137-2:2015 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose	27 May 2024
7.	EN ISO 11607-1:2020 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier	27 May 2024

	systems and packaging systems	
8.	EN ISO 11607-2:2020 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	27 May 2024
9.	EN ISO 11737-1:2018 Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products	27 May 2024
10.	EN ISO 11737-2:2020 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process	27 May 2024
11.	EN ISO 13408-1:2015 Aseptic processing of health care products - Part 1: General requirements	27 May 2024
12.	EN ISO 13408-2:2018 Aseptic processing of health care products - Part 2: Filtration	27 May 2024
13.	EN ISO 13408-3:2011 Aseptic processing of health care products - Part 3: Lyophilization	27 May 2024
14.	EN ISO 13408-4:2011 Aseptic processing of health care products - Part 4: Clean-in-place technologies	27 May 2024
15.	EN ISO 13408-5:2011 Aseptic processing of health care products - Part 5: Sterilization in place	27 May 2024
16.	EN ISO 13408-6:2011+A1:2013 Aseptic processing of health care products - Part 6: Isolator systems	27 May 2024
17.	EN ISO 13408-7:2015	27 May 2024

	Aseptic processing of health care products - Part 7: Alternative processes for medical devices and combination products	
18.	EN ISO 13485:2016+AC:2018 Medical devices - Quality management systems - Requirements for regulatory purposes	27 May 2024
19.	EN 13532:2002 General requirements for *in vitro* diagnostic medical devices for self-testing	27 May 2024
20.	EN 13612:2002+AC:2002 Performance evaluation of *in vitro* diagnostic medical devices	27 May 2024
21.	EN 13641:2002 Elimination or reduction of risk of infection related to *in vitro* diagnostic reagents	27 May 2024
22.	EN 13975:2003 Sampling procedures used for acceptance testing of *in vitro* diagnostic medical devices - Statistical aspects	27 May 2024
23.	EN 14136:2004 Use of external quality assessment schemes in the assessment of the performance of *in vitro* diagnostic examination procedures	27 May 2024
24.	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	27 May 2024
25.	EN ISO 14971:2019 Medical devices - Application of risk management to medical devices	27 May 2024
26.	EN ISO 15193:2009 *In vitro* diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for content and presentation of reference	27 May 2024

	measurement procedures	
27.	EN ISO 15194:2009 *In vitro* diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for certified reference materials and the content of supporting documentation	27 May 2024
28.	EN ISO 15197:2015 *In vitro* diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus	27 May 2024
29.	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	27 May 2024
30.	EN ISO 17511:2003 *In vitro* diagnostic medical devices - requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples	27 May 2024
31.	EN ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices	27 May 2024
32.	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	27 May 2024
33.	EN ISO 18113-1:2011 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements	27 May 2024
34.	EN ISO 18113-2:2011 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: *In*	27 May 2024

	vitro diagnostic reagents for professional use	
35.	EN ISO 18113-3:2011 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: *In vitro* diagnostic instruments for professional use	27 May 2024
36.	EN ISO 18113-4:2011 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 4: *In vitro* diagnostic reagents for self-testing	27 May 2024
37.	EN ISO 18113-5:2011 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 5: *In vitro* diagnostic instruments for self-testing	27 May 2024
38.	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	27 May 2024
39.	EN ISO 23640:2015 *In vitro* diagnostic medical devices - Evaluation of stability of *in vitro* diagnostic reagents	27 May 2024
40.	EN ISO 25424:2019 Sterilization of health care products - Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices	27 May 2024
41.	EN 61326-1:2013 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements	27 May 2024
42.	EN 61326-2-6:2013 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - *In vitro* diagnostic (IVD) medical equipment	27 May 2024

43.	EN 61010-1:2010+A1:2019+AC:2019 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements	27 May 2024
44.	EN 61010-2-101:2017 Safety requirements for electrical equipment for measurement, control and laboratory use - Part 2-101: Particular requirements for *in vitro* diagnostic (IVD) medical equipment	27 May 2024
45.	EN 62304:2006+A1:2015 Medical device software - Software life-cycle processes	27 May 2024
46.	EN 62366-1:2015+AC:2015+AC:2016+A1:2020 Medical devices - Application of usability engineering to medical devices	27 May 2024

Table 2: List of new harmonised standards to be drafted and deadlines for their adoption

Reference information		**Deadline for the adoption**
1.	Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices (ISO 17664-1)	27 May 2024
2.	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 (ISO 17664-2)	27 May 2024
3.	*In vitro* diagnostic medical devices - Clinical performance studies using specimens from human subjects - Good study practice (ISO 20916)	27 May 2024

ANNEX III

Requirements for the standards referred to in Article 1

Part A. General requirements

1. Legal requirements to be supported by the harmonised standards

The harmonised standards shall support application of relevant safety and performance requirements for medical devices and *in vitro* diagnostic medical devices for human use and system and process requirements for economic operators and sponsors of clinical investigations and performance studies set out in Regulations (EU) 2017/745 and (EU) 2017/746.

The harmonised standards shall provide detailed technical, scientific, processual or methodological specifications of safety and performance requirements with the purpose of allowing compliance with relevant requirements of Regulations (EU) 2017/745 and (EU) 2017/746. Where appropriate, the harmonised standards shall include methods to verify compliance with such specifications.

The structure of a harmonised standard shall be such that a clear distinction can be made between its clauses and sub-clauses, which are necessary for compliance with the safety and performance requirements of Regulation (EU) 2017/745 or Regulation (EU) 2017/746 that the standard aims to cover and those which are not. The relationship between the clauses and sub-clauses of a harmonised standard and the requirements of Regulation (EU) 2017/745 or Regulation (EU) 2017/746 shall be indicated in the Annexes Z to each standard. The relevant requirements of Regulations (EU) 2017/745 and (EU) 2017/746 shall be taken into account from the beginning and throughout the process of developing of the standards.

The normative body of a harmonised standard shall not:

(a) make any references to Regulation (EU) 2017/745 or Regulation (EU) 2017/746 or reproduce their requirements;

(b) contradict any definitions set out in Regulations (EU) 2017/745 and (EU) 2017/746 or define any legally relevant terms not defined in those Regulations.

Where a definition in a harmonised standard differs from a definition of the same term set out in Regulation (EU) 2017/745 or Regulation (EU) 2017/746, the differences shall be indicated in the foreword of that standard and in its Annex Z. That Annex shall also state that, for the purpose of using the standard in support of the requirements set out in Regulations (EU) 2017/745 and (EU) 2017/746, the definitions set out in those Regulations prevail.

Each harmonised standard developed on the basis of the standardisation request referred to in Article 1 shall refer to this Decision.

Each revised harmonised standard shall contain information on significant changes introduced in that standard.

2. Legal requirements to be covered by an individual harmonised standard

When one of the harmonised standards listed in Annex I or in Annex II does not cover all relevant requirements applicable to devices or system or process requirements falling under its scope, or when it covers such requirements only partially, that standard shall include in its Annex Z information on the relevant applicable requirements or parts thereof that are not covered by it.

Where appropriate, the harmonised standard shall include information as to whether a particular requirement is addressed with regard to the design, manufacturing, or packaging of the device.

3. Reduction of risk

The specifications of harmonised standards concerning the reduction of risk which may be associated with the device shall take into account the general requirements laid down in point 2 of Chapter I of Annex I to Regulation (EU) 2017/745 and in point 2 of Chapter I of Annex I to Regulation (EU) 2017/746 to reduce risks as far as possible without adversely affecting the benefit-risk ratio.

4. Normative references

Normative references included in a harmonised standard shall be clear and specific and ensure identification of all specifications covered by the standard. Where a standard refers to another standard or a clause in that standard, and that standard or clause contains a further normative reference or references ('a normative reference chain'), the whole normative reference chain shall be clear and specific. Normative reference chains shall be avoided.

Clauses of a standard, which do not provide for technical, scientific or methodological specifications, but are limited to a normative reference to another standard or a clause in that standard shall not claim coverage of the legal requirements that are addressed in the standard normatively referred to.

Standards which do not ensure compliance with legal requirements on their own, but require application of another standard, shall contain a clear statement to that effect. They shall not claim coverage of the legal requirements covered by that other standard.

Standards containing normative references to undated standards shall indicate the dated version of any such referenced standard.

5. Publicly available description of the meaning of symbols

Where a harmonised standard provides a description of the meaning of symbols to be used in the information supplied by the manufacturer that description shall be made publicly available. Public availability of such descriptions shall not affect any copyright to a harmonised standard or its parts.

Part B. Specific requirements

1. Requirements for all harmonised standards listed in Annexes I and II

The harmonised standards shall ensure safety and effectiveness of devices and a high level of protection of health and safety of patients, users or others persons. They shall reflect the generally acknowledged state of the art.

2. Requirements for certain specific standards listed in Annexes I and II

2.1 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (EN ISO 10993-7:2008+AC:2009) and Part 17: Establishment of allowable limits for leachable substances (EN ISO 10993-17:2009)

In the standard EN ISO 10993-7:2008+AC:2009, the method of calculation of residue limits for ethylene oxide sterilant laid down in point 4.3.1 of that standard shall be modified in such a way as to take into account also patients with a weight lower/higher

than 70 kg, in particular neonates and other patients with a weight substantially below the adults' standard weight of 70 kg.

In the standard EN ISO 10993-17:2009, the method of calculation of concomitant exposure to ethylene oxide sterilant laid down in points 6.2.2 and 6.3.2 of that standard shall be modified in such a way as to take into account certain clinical situations involving use of several medical devices in neonates with a bodyweight lower than 3,5 kg.

2.2 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (EN ISO 15223-1:2016)

The existing standard EN ISO 15223-1:2016 shall be modified by the addition of a symbol which indicates that a device is a medical device or an *in vitro* diagnostic medical device to facilitate application of section 23.2(q) of Chapter III of Annex I to Regulation (EU) 2017/745 or section 20.2(e) of Chapter III of Annex I to Regulation (EU) 2017/746, as appropriate.

2.3 Sharps injury protection - Requirements and test methods - Sharps protection features for single-use hypodermic needles, introducers for catheters and needles used for blood sampling (EN ISO 23908:2013)

The existing standard EN ISO 23908:2013 shall be modified by describing technical solutions for safety-engineered mechanisms to be applied in design and manufacture of devices to ensure compliance with points 11.1 and 22.2 of Chapter II of Annex I to Regulation (EU) 2017/745. The standard shall apply to devices which are intended to be used for administration and/or extraction of body/blood fluids and/or medicinal substances.

2.4 Health software - Part 1: General requirements for product safety (EN 82304-1:2017)

The existing standard EN 82304-1:2017 shall be modified by ensuring a clear separation between products (software) which fall within the scope of Regulation (EU) 2017/745 and those that do not, ensuring that there is no ambiguity on its legal effect and on which products could claim presumption of conformity on its basis.