CONSOLIDATED TEXT:

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)

Initial legal act:

- Commission Implementing Decision of 14.4.2021 (C(2021)2406) – Standardisation request M/575
  https://ec.europa.eu/growth/tools-databases/enorm/mandate/575_en

Amended by:

- Commission Implementing Decision of 31.1.2023 (C(2023)694) – Standardisation request M/575 Amd 1
  https://ec.europa.eu/growth/tools-databases/enorm/mandate/575Amd1_en
- Commission Implementing Decision of 27.5.2024 (C(2024)3371) – Standardisation request M/575 Amd 2
  https://ec.europa.eu/growth/tools-databases/enorm/mandate/575Amd2_en

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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 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

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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).

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).

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 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.

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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.

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 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.

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

(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.

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

[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.

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 2028.

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 2028

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

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 Sterilization - Steam sterilizers - Large sterilizers	27 May 2024
2.	EN 455-1 Medical gloves for single use - Part 1: Requirements and testing for freedom from holes	27 May 2028
3.	EN 455-2 Medical gloves for single use - Part 2: Requirements and testing for physical properties	27 May 2028
4.	EN 455-3 Medical gloves for single use - Part 3: Requirements and testing for biological evaluation	27 May 2028
5.	EN 455-4 Medical gloves for single use - Part 4: Requirements and testing for shelf life determination	27 May 2028
6.	EN 556-1 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 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 ISO 1135-4 Transfusion equipment for medical use - Part 4: Transfusion sets for single use, gravity feed	27 May 2028

9.	EN ISO 1135-5 Transfusion equipment for medical use - Part 5: Transfusion sets for single use with pressure infusion apparatus	27 May 2028
10.	EN 1422 Sterilizers for medical purposes - Ethylene oxide sterilizers - Requirements and test methods	27 May 2028
11.	EN 1865-1 Patient handling equipment used in road ambulances - Part 1: General stretcher systems and patient handling equipment	27 May 2028
12.	EN 1865-2 Patient handling equipment used in road ambulances - Part 2: Power assisted stretcher	27 May 2024
13.	EN 1865-3 Patient handling equipment used in road ambulances - Part 3: Heavy duty stretcher	27 May 2028
14.	EN 1865-4 Patient handling equipment used in road ambulances - Part 4: Foldable patient transfer chair	27 May 2028
15.	EN 1985 Walking aids - General requirements and test method	27 May 2028
16.	EN ISO 4074 Natural rubber latex male condoms - Requirements and test methods	27 May 2028
17.	EN ISO 5359 Anaesthetic and respiratory equipment - Low-pressure hose assemblies for use with medical gases	27 May 2028
18.	EN ISO 5840-1 Cardiovascular implants - Cardiac valve prostheses - Part 1: General requirements	27 May 2028
19.	EN ISO 5840-2	27 May 2028

	Cardiovascular implants - Cardiac valve prostheses - Part 2: Surgically implanted heart valve substitutes	
20.	EN ISO 5840-3 Cardiovascular implants - Cardiac valve prostheses - Part 3: Heart valve substitutes implanted by transcatheter techniques	27 May 2028
21.	EN ISO 7010 Graphical symbols - Safety colours and safety signs - Registered safety signs	27 May 2028
22.	EN ISO 7197 Neurosurgical implants - Sterile, single-use hydrocephalus shunts and components	27 May 2028
23.	EN ISO 7396-1 Medical gas pipeline systems - Part 1: Pipeline systems for compressed medical gases and vacuum	27 May 2028
24.	EN ISO 7396-2 Medical gas pipeline systems - Part 2: Anaesthetic gas scavenging disposal systems	27 May 2028
25.	EN ISO 9713 Neurosurgical implants - Self-closing intracranial aneurysm clips	27 May 2028
26.	EN ISO 10328 Prosthetics - Structural testing of lower-limb prostheses - Requirements and test methods	27 May 2028
27.	EN ISO 10524-1 Pressure regulators for use with medical gases - Part 1: Pressure regulators and pressure regulators with flow-metering devices	27 May 2028
28.	EN ISO 10524-2 Pressure regulators for use with medical gases - Part 2: Manifold and line pressure regulators	27 May 2028
29.	EN ISO 10524-3 Pressure regulators for use with medical gases - Part 3:	27 May 2028

	Pressure regulators integrated with cylinder valves (VIPRs)	
30.	EN ISO 10535 Hoists for the transfer of disabled persons - Requirements and test methods	27 May 2028
31.	EN ISO 10651-4 Lung ventilators - Part 4: Particular requirements for user-powered resuscitators	27 May 2028
32.	EN ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	27 May 2028
33.	EN ISO 10993-3 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	27 May 2028
34.	EN ISO 10993-4 Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood	27 May 2028
35.	EN ISO 10993-5 Biological evaluation of medical devices - Part 5: Tests for *in vitro* cytotoxicity	27 May 2028
36.	EN ISO 10993-6 Biological evaluation of medical devices - Part 6: Tests for local effects after implantation	27 May 2028
37.	EN ISO 10993-7 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals	27 May 2028
38.	EN ISO 10993-9 Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products	27 May 2024
39.	EN ISO 10993-10	27 May 2024

	Biological evaluation of medical devices - Part 10: Tests for skin sensitization	
40.	EN ISO 10993-11 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	27 May 2028
41.	EN ISO 10993-12 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials	27 May 2024
42.	EN ISO 10993-13 Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices	27 May 2028
43.	EN ISO 10993-14 Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products from ceramics	27 May 2028
44.	EN ISO 10993-15 Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys	27 May 2024
45.	EN ISO 10993-16 Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables	27 May 2028
46.	EN ISO 10993-17 Biological evaluation of medical devices - Part 17: Toxicological risk assessment of medical device constituents	27 May 2024
47.	EN ISO 10993-18 Biological evaluation of medical devices - Part 18: Chemical characterization of materials	27 May 2024
48.	EN ISO 11135 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and	27 May 2024

	routine control of a sterilization process for medical devices	
49.	EN ISO 11137-1 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
50.	EN ISO 11137-2 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose	27 May 2024
51.	EN ISO 11140-1 Sterilization of health care products - Chemical indicators - Part 1: General requirements	27 May 2028
52.	EN ISO 11140-3 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 2028
53.	EN ISO 11140-4 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 2028
54.	EN ISO 11197 Medical supply units	27 May 2028
55.	EN ISO 11607-1 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	27 May 2024
56.	EN ISO 11607-2 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	27 May 2024
57.	EN ISO 11737-1 Sterilization of medical devices - Microbiological	27 May 2024

	methods - Part 1: Determination of a population of microorganisms on products	
58.	EN ISO 11737-2 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
59.	EN ISO 11810 Lasers and laser-related equipment - Test method and classification for the laser resistance of surgical drapes and/or patient protective covers - Primary ignition, penetration, flame spread and secondary ignition	27 May 2028
60.	EN ISO 11990 Lasers and laser-related equipment - Determination of laser resistance of tracheal tube shaft and tracheal cuffs	27 May 2028
61.	EN 12183 Manual wheelchairs - Requirements and test methods	27 May 2028
62.	EN 12184 Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods	27 May 2028
63.	EN ISO 12417-1 Cardiovascular implants and extracorporeal systems - Vascular device-drug combination products - Part 1: General requirements	27 May 2028
64.	EN ISO 12870 Ophthalmic optics - Spectacle frames - Requirements and test methods	27 May 2024
65.	EN 13060 Small steam sterilizers	27 May 2028
66.	EN ISO 13408-1 Aseptic processing of health care products - Part 1: General requirements	27 May 2024
67.	EN ISO 13408-2	27 May 2028

	Aseptic processing of health care products - Part 2: Filtration	
68.	EN ISO 13408-3 Aseptic processing of health care products - Part 3: Lyophilization	27 May 2028
69.	EN ISO 13408-4 Aseptic processing of health care products - Part 4: Clean-in-place technologies	27 May 2028
70.	EN ISO 13408-5 Aseptic processing of health care products - Part 5: Sterilization in place	27 May 2028
71.	EN ISO 13408-6 Aseptic processing of health care products - Part 6: Isolator systems	27 May 2024
72.	EN ISO 13408-7 Aseptic processing of health care products - Part 7: Alternative processes for medical devices and combination products	27 May 2028
73.	EN ISO 13485 Medical devices - Quality management systems - Requirements for regulatory purposes	27 May 2024
74.	EN 13624 Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal or yeasticidal activity in the medical area - Test method and requirements (phase 2, step 1)	27 May 2028
75.	EN 13718-1 Medical vehicles and their equipment - Air ambulances - Part 1: Requirements for medical devices used in air ambulances	27 May 2028
76.	EN 13727 Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity in the medical area - Test method and	27 May 2028

	requirements (phase 2, step 1)	
77.	EN 13795-1 Surgical clothing and drapes - Requirements and test methods - Part 1: Surgical drapes and gowns	27 May 2028
78.	EN 13795-2 Surgical clothing and drapes - Requirements and test methods - Part 2: Clean air suits	27 May 2028
79.	EN 13976-1 Rescue systems - Transportation of incubators - Part 1: Interface requirements	27 May 2028
80.	EN 13976-2 Rescue systems - Transportation of incubators - Part 2: System requirements	27 May 2028
81.	EN 14139 Ophthalmic optics - Specifications for ready-to-wear spectacles	27 May 2028
82.	EN ISO 14155 Clinical investigation of medical devices for human subjects - Good clinical practice	27 May 2028
83.	EN ISO 14160 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
84.	EN 14180 Sterilizers for medical purposes - Low temperature steam and formaldehyde sterilizers - Requirements and testing	27 May 2028
85.	EN 14348 Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area	27 May 2028

	including instrument disinfectants - Test methods and requirements (phase 2, step 1)	
86.	EN 14476 Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of virucidal activity in the medical area - Test method and requirements (Phase 2/Step 1)	27 May 2028
87.	EN 14561 Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area - Test method and requirements (phase 2, step 2)	27 May 2028
88.	EN 14562 Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of fungicidal or yeasticidal activity for instruments used in the medical area - Test method and requirements (phase 2, step 2)	27 May 2028
89.	EN 14563 Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of mycobactericidal or tuberculocidal activity of chemical disinfectants used for instruments in the medical area - Test method and requirements (phase 2, step 2)	27 May 2028
90.	EN ISO 14602 Non-active surgical implants - Implants for osteosynthesis - Particular requirements	27 May 2028
91.	EN ISO 14607 Non-active surgical implants - Mammary implants - Particular requirements	27 May 2028
92.	EN ISO 14630 Non-active surgical implants - General requirements	27 May 2028
93.	EN 14683 Medical face masks - Requirements and test methods	27 May 2028
94.	EN 14885	27 May 2028

	Chemical disinfectants and antiseptics - Application of European standards for chemical disinfectants and antiseptics	
95.	EN ISO 14889 Ophthalmic optics - Spectacle lenses - Fundamental requirements for uncut finished lenses	27 May 2028
96.	EN ISO 14937 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 2028
97.	EN ISO 14971 Medical devices - Application of risk management to medical devices	27 May 2024
98.	EN ISO 15001 Anaesthetic and respiratory equipment - Compatibility with oxygen	27 May 2028
99.	EN ISO 15004-1 Ophthalmic instruments - Fundamental requirements and test methods - Part 1: General requirements applicable to all ophthalmic instruments	27 May 2028
100.	EN ISO 15223-1 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	27 May 2028
101.	EN ISO 15883-1 Washer-disinfectors - Part 1: General requirements, terms and definitions and tests	27 May 2028
102.	EN ISO 15883-2 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 2028
103.	EN ISO 15883-3	27 May 2028

	Washer-disinfectors - Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers	
104.	EN ISO 15883-4 Washer-disinfectors - Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes	27 May 2028
105.	EN ISO 15883-6 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 2028
106.	EN ISO 15883-7 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 2028
107.	EN ISO 16061 Instruments for use in association with non-active surgical implants - General requirements	27 May 2028
108.	EN 16615 Chemical disinfectants and antiseptics - Quantitative test method for the evaluation of bactericidal and yeasticidal activity on non-porous surfaces with mechanical action employing wipes in the medical area (4- field test) - Test method and requirements (phase 2, step 2)	27 May 2028
109.	EN 16616 Chemical disinfectants and antiseptics - Chemical-thermal textile disinfection - Test method and requirements (phase 2, step 2)	27 May 2028
110.	EN 16777 Chemical disinfectants and antiseptics - Quantitative non-porous surface test without mechanical action for the evaluation of virucidal activity of chemical disinfectants used in the medical area - Test method and requirements (phase 2/step 2)	27 May 2028

111.	EN 17111 Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of virucidal activity for instruments used in the medical area - Test method and requirements (phase 2, step 2)	27 May 2028
112.	EN 17126 Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of sporicidal activity of chemical disinfectants in the medical area - Test method and requirements (phase 2, step 1)	27 May 2028
113.	EN 17387 Chemical disinfectants and antiseptics - Quantitative test for the evaluation of bactericidal and yeasticidal and/or fungicidal activity of chemical disinfectants in the medical area on non-porous surfaces without mechanical action - Test method and requirements (phase 2, step 2)	27 May 2028
114.	EN ISO 17510 Medical devices - Sleep apnoea breathing therapy - Masks and application accessories	27 May 2028
115.	EN ISO 17664 Sterilisation of medical devices - Information to be provided by the medical device manufacturer for the processing of medical devices	27 May 2024
116.	EN ISO 17665 Sterilization of health care products - Moist heat - Requirements for the development, validation and routine control of a sterilization process for medical devices	27 May 2024
117.	EN ISO 18562-1 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 1: Evaluation and testing within a risk management process	27 May 2024
118.	EN ISO 18562-2 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 2: Tests for emissions	27 May 2024

	of particulate matter	
119.	EN ISO 18562-3 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 3: Tests for emissions of volatile organic compounds (VOCs)	27 May 2024
120.	EN ISO 18562-4 Biocompatibility evaluation of breathing gas pathways in healthcare applications - Part 4: Tests for leachables in condensate	27 May 2024
121.	EN ISO 20857 Sterilization of health care products - Dry heat - Requirements for the development, validation and routine control of a sterilization process for medical devices	27 May 2028
122.	EN ISO 21534 Non-active surgical implants - Joint replacement implants - Particular requirements	27 May 2028
123.	EN ISO 21535 Non-active surgical implants - Joint replacement implants - Specific requirements for hip-joint replacement implants	27 May 2024
124.	EN ISO 21536 Non-active surgical implants - Joint replacement implants - Specific requirements for knee-joint replacement implants	27 May 2024
125.	EN ISO 21987 Ophthalmic optics - Mounted spectacle lenses	27 May 2028
126.	EN ISO 22442-1 Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk management	27 May 2028
127.	EN ISO 22442-2 Medical devices utilizing animal tissues and their derivatives - Part 2: Controls on sourcing, collection and handling	27 May 2028

128.	EN ISO 22442-3 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 2028
129.	EN ISO 22523 External limb prostheses and external orthoses - Requirements and test methods	27 May 2028
130.	EN ISO 22675 Prosthetics - Testing of ankle-foot devices and foot units - Requirements and test methods	27 May 2024
131.	EN ISO 23328-1 Breathing system filters for anaesthetic and respiratory use - Part 1: Salt test method to assess filtration performance	27 May 2028
132.	EN ISO 23328-2 Breathing system filters for anaesthetic and respiratory use - Part 2: Non-filtration aspects	27 May 2028
133.	EN ISO 23747 Anaesthetic and respiratory equipment - Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans	27 May 2028
134.	EN ISO 23908 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 2028
135.	EN ISO 25424 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
136.	EN ISO 25539-1 Cardiovascular implants - Endovascular devices - Part	27 May 2028

	1: Endovascular prostheses	
137.	EN ISO 25539-2 Cardiovascular implants - Endovascular devices - Part 2: Vascular stents	27 May 2028
138.	EN ISO 25539-3 Cardiovascular implants - Endovascular devices - Part 3: Vena cava filters	27 May 2028
139.	EN ISO 26782 Anaesthetic and respiratory equipment - Spirometers intended for the measurement of time forced expired volumes in humans	27 May 2028
140.	EN 50637 Medical electrical equipment - Particular requirements for the basic safety and essential performance of medical beds for children	27 May 2028
141.	EN 60118-0 Electroacoustics - Hearing aids - Part 0: Measurement of the performance characteristics of hearing aids	27 May 2024
142.	EN IEC 60118-13 Electroacoustics - Hearing aids - Part 13: Requirements and methods of measurement for electromagnetic immunity to mobile digital wireless devices	27 May 2028
143.	EN 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	27 May 2028
144.	EN 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	27 May 2028
145.	EN 60601-1-3 Medical electrical equipment - Part 1-3: General	27 May 2028

	requirements for basic safety and essential performance - Collateral standard: Radiation protection in diagnostic X-ray equipment	
146.	EN 60601-1-6 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	27 May 2028
147.	EN 60601-1-8: 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 2028
148.	EN 60601-1-10 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 2028
149.	EN 60601-1-11 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 2028
150.	EN 60601-1-12 Medical electrical equipment - Part 1-12: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment	27 May 2028
151.	EN 60601-2-1 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 2028
152.	EN IEC 60601-2-2	27 May 2024

	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	
153.	EN 60601-2-3 Medical electrical equipment - Part 2-3: Particular requirements for the basic safety and essential performance of short-wave therapy equipment	27 May 2028
154.	EN 60601-2-4 Medical electrical equipment - Part 2-4: Particular requirements for the basic safety and essential performance of cardiac defibrillators	27 May 2028
155.	EN 60601-2-5 Medical electrical equipment - Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment	27 May 2028
156.	EN 60601-2-6 Medical electrical equipment - Part 2-6: Particular requirements for the basic safety and essential performance of microwave therapy equipment	27 May 2028
157.	EN 60601-2-8 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 2028
158.	EN 60601-2-10 Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators	27 May 2024
159.	EN 60601-2-11 Medical electrical equipment - Part 2-11: Particular requirements for the basic safety and essential performance of gamma beam therapy equipment	27 May 2028
160.	EN IEC 60601-2-16 Medical electrical equipment - Part 2-16: Particular requirements for the basic safety and essential	27 May 2028

	performance of haemodialysis, haemodiafiltration and haemofiltration equipment	
161.	EN 60601-2-17 Medical electrical equipment - Part 2-17: Particular requirements for the basic safety and essential performance of automatically-controlled brachytherapy afterloading equipment	27 May 2028
162.	EN 60601-2-18 Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment	27 May 2028
163.	EN IEC 60601-2-19 Medical electrical equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators	27 May 2028
164.	EN IEC 60601-2-20 Medical electrical equipment - Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators	27 May 2028
165.	EN IEC 60601-2-21 Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers	27 May 2028
166.	EN IEC 60601-2-22 Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment	27 May 2028
167.	EN 60601-2-23 Medical electrical equipment - Part 2-23: Particular requirements for the basic safety and essential performance of transcutaneous partial pressure monitoring equipment	27 May 2028
168.	EN 60601-2-24 Medical electrical equipment - Part 2-24: Particular requirements for the basic safety and essential	27 May 2028

	performance of infusion pumps and controllers	
169.	EN 60601-2-25 Medical electrical equipment - Part 2-25: Particular requirements for the basic safety and essential performance of electrocardiographs	27 May 2028
170.	EN 60601-2-27 Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment	27 May 2028
171.	EN IEC 60601-2-28 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 2028
172.	EN 60601-2-29 Medical electrical equipment - Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators	27 May 2028
173.	EN IEC 60601-2-31 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 2028
174.	EN 60601-2-33 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
175.	EN 60601-2-34 Medical electrical equipment - Part 2-34: Particular requirements for the basic safety and essential performance of invasive blood pressure monitoring equipment	27 May 2028
176.	EN 60601-2-36 Medical electrical equipment - Part 2-36: Particular	27 May 2028

	requirements for the basic safety and essential performance of equipment for extracorporeally induced lithotripsy	
177.	EN 60601-2-37 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment	27 May 2028
178.	EN IEC 60601-2-39 Medical electrical equipment - Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment	27 May 2028
179.	EN 60601-2-40 Medical electrical equipment - Part 2-40: Particular requirements for the basic safety and essential performance of electromyographs and evoked response equipment	27 May 2028
180.	EN 60601-2-41 Medical electrical equipment - Part 2-41: Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for diagnosis	27 May 2028
181.	EN 60601-2-43 Medical electrical equipment - Part 2-43: Particular requirements for the basic safety and essential performance of X-ray equipment for interventional procedures	27 May 2028
182.	EN 60601-2-44 Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography	27 May 2028
183.	EN 60601-2-45 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

184.	EN IEC 60601-2-46 Medical electrical equipment - Part 2-46: Particular requirements for the basic safety and essential performance of operating tables	27 May 2028
185.	EN 60601-2-47 Medical electrical equipment - Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems	27 May 2028
186.	EN 60601-2-50 Medical electrical equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment	27 May 2028
187.	EN 60601-2-52 Medical electrical equipment - Part 2-52: Particular requirements for the basic safety and essential performance of medical beds	27 May 2028
188.	EN 60601-2-54 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
189.	EN IEC 60601-2-57 Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use	27 May 2024
190.	EN 60601-2-62 Medical electrical equipment - Part 2-62: Particular requirements for the basic safety and essential performance of high intensity therapeutic ultrasound (HITU) equipment	27 May 2028
191.	EN 60601-2-63 Medical electrical equipment - Part 2-63: Particular requirements for the basic safety and essential	27 May 2028

	performance of dental extra-oral X-ray equipment	
192.	EN 60601-2-64 Medical electrical equipment - Part 2-64: Particular requirements for the basic safety and essential performance of light ion beam medical electrical equipment	27 May 2028
193.	EN 60601-2-65 Medical electrical equipment - Part 2-65: Particular requirements for the basic safety and essential performance of dental intra-oral X-ray equipment	27 May 2028
194.	EN IEC 60601-2-66 Medical electrical equipment - Part 2-66: Particular requirements for the basic safety and essential performance of hearing aids and hearing aid systems	27 May 2028
195.	EN 60601-2-68 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 2028
196.	EN IEC 60601-2-75 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
197.	EN IEC 60601-2-76 Medical electrical equipment - Part 2-76: Particular requirements for the basic safety and essential performance of low energy ionized gas haemostasis equipment	27 May 2028
198.	EN IEC 60601-2-83 Medical electrical equipment - Part 2-83: Particular requirements for the basic safety and essential performance of home light therapy equipment	27 May 2024
199.	EN 61010-1	27 May 2028

	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 1: General requirements	
200.	EN IEC 61010-2-040 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-040: Particular requirements for sterilizers and washer-disinfectors used to treat medical materials	27 May 2028
201.	EN 61326-1 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements	27 May 2028
202.	EN 62083 Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems	27 May 2028
203.	EN 62304 Medical device software - Software life-cycle processes	27 May 2028
204.	EN 62366-1 Medical devices - Application of usability engineering to medical devices	27 May 2028
205.	EN 80001-1 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 2028
206.	EN ISO 80369-1 Small-bore connectors for liquids and gases in healthcare applications - Part 1: General requirements	27 May 2028
207.	EN ISO 80369-3 Small-bore connectors for liquids and gases in healthcare applications - Part 3: Connectors for enteral applications	27 May 2028
208.	EN ISO 80369-5	27 May 2028

	Small-bore connectors for liquids and gases in healthcare applications - Part 5: Connectors for limb cuff inflation applications	
209.	EN ISO 80369-6 Small bore connectors for liquids and gases in healthcare applications - Part 6: Connectors for neuraxial applications	27 May 2028
210.	EN ISO 80369-7 Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications	27 May 2028
211.	EN ISO 80369-20 Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods	27 May 2028
212.	EN ISO 80601-2-12 Medical electrical equipment - Part 2-12: Particular requirements for basic safety and essential performance of critical care ventilators	27 May 2028
213.	EN ISO 80601-2-13 Medical electrical equipment - Part 2-13: Particular requirements for basic safety and essential performance of an anaesthetic workstation	27 May 2028
214.	EN IEC 80601-2-26 Medical electrical equipment - Part 2-26: Particular requirements for the basic safety and essential performance of electroencephalographs	27 May 2028
215.	EN IEC 80601-2-30 Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers	27 May 2028
216.	EN IEC 80601-2-35 Medical electrical equipment - Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads	27 May 2028

	and mattresses and intended for heating in medical use	
217.	EN IEC 80601-2-49 Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment	27 May 2028
218.	EN ISO 80601-2-56 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement	27 May 2028
219.	EN 80601-2-58 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 2028
220.	EN IEC 80601-2-59 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 2028
221.	EN IEC 80601-2-60 Medical electrical equipment - Part 2-60: Particular requirements for the basic safety and essential performance of dental equipment	27 May 2028
222.	EN ISO 80601-2-69 Medical electrical equipment - Part 2-69: Particular requirements for basic safety and essential performance of oxygen concentrator equipment	27 May 2028
223.	EN IEC 80601-2-71 Medical electrical equipment - Part 2-71: Particular requirements for the basic safety and essential performance of functional near-infrared spectroscopy (NIRS) equipment	27 May 2028
224.	EN IEC 80601-2-77 Medical electrical equipment - Part 2-77: Particular	27 May 2028

	requirements for the basic safety and essential performance of robotically assisted surgical equipment	
225.	EN IEC 80601-2-78 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 2028
226.	EN 82304-1 Health Software - Part 1: General requirements for product safety	27 May 2028

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

Reference information		Deadline for the adoption
1.	Patient handling equipment used in road ambulances - Part 6: Power chairs (prEN 1865-6)	27 May 2024
2.	Anaesthetic reservoir bags (EN ISO 5362)	27 May 2028
3.	Anaesthetic and respiratory equipment - Breathing sets and connectors (EN ISO 5367)	27 May 2028
4.	Medical gas pipeline systems - Part 3: Proportioning units for the production of synthetic medical air (EN ISO 7396-3)	27 May 2028
5.	Lung ventilators for medical use - Particular requirements for basic safety and essential performance - Part 5: Gas-powered emergency resuscitators (EN ISO 10651-5)	27 May 2028
6.	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23)	27 May 2024
7.	Sterilization of health care products - Chemical indicators - Part 6: Type 2 indicators and process challenge devices for use in performance testing of small steam sterilizers (EN ISO 11140-6)	27 May 2028
8.	Sterilization of health care products - Microbiological methods - Part 3: Bacterial endotoxin testing (EN ISO 11737-3)	27 May 2028

9.	Sterilization of health care products - Radiation - Substantiation of selected sterilization dose: Method VDmaxSD (ISO 13004)	27 May 2028
10.	Stainless steel steam boilers (prEN 14222)	27 May 2028
11.	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 2028
12.	Implants for surgery - Active implantable medical devices - Part 2: Cardiac pacemakers (ISO 14708-2)	27 May 2028
13.	Implants for surgery - Active implantable medical devices - Part 3: Implantable neurostimulators (ISO 14708-3)	27 May 2028
14.	Implants for surgery - Active implantable medical devices - Part 4: Implantable infusion pumps (ISO 14708-4)	27 May 2028
15.	Implants for surgery - Active implantable medical devices - Part 5: Circulatory support devices (ISO 14708-5)	27 May 2028
16.	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 2028
17.	Implants for surgery - Active implantable medical devices - Part 7: Particular requirements for cochlear and auditory brainstem implant systems (ISO 14708-7)	27 May 2028
18.	Washer-disinfectors - Part 5: Performance requirements and test method criteria for demonstrating cleaning efficacy (ISO 15883-5)	27 May 2028
19.	Systems for evacuation of plume generated by medical devices (EN ISO 16571)	27 May 2028
20.	Sterilizers for medical purposes - Low temperature vapourized hydrogen peroxide sterilizers - Requirements and testing (prEN 17180)	27 May 2028
21.	Anaesthetic and respiratory equipment - Respiratory therapy tubing and connectors (ISO 17256)	27 May 2028
22.	Assistive products for personal hygiene that support	27 May 2028

	users - Requirements and test methods (ISO 17966)	
23.	Anaesthetic and respiratory equipment - General requirements for airways and related equipment (ISO 18190)	27 May 2028
24.	Medical devices - Connectors for reservoir delivery systems for healthcare applications (ISO 18250)	27 May 2028
25.	Manufacture of cell-based health care products - Control of microbial risks during processing (ISO 18362)	27 May 2028
26.	Transportable liquid oxygen systems for medical use - Common requirements and particular requirements for base units (EN ISO 18777-1)	27 May 2028
27.	Transportable liquid oxygen systems for medical use - Particular requirements for portable units (EN ISO 18777-2)	27 May 2028
28.	Clinical evaluation of medical devices (EN ISO 18969)	27 May 2028
29.	Anaesthetic and respiratory equipment - Fire-activated oxygen shut-off devices for use during oxygen therapy (ISO 19211)	27 May 2028
30.	Medical devices - Information to be provided by the manufacturer (ISO 20417)	27 May 2028
31.	Anaesthetic and respiratory equipment - Passive humidifiers (EN ISO 20789)	27 May 2028
32.	Assistive products - General requirements and test methods (ISO 21856)	27 May 2028
33.	Lasers and laser-related equipment - Test methods for laser-induced damage threshold - Classification of medical beam delivery systems (ISO 22248)	27 May 2028
34.	Sterilization of health care products - Low temperature vaporized hydrogen peroxide - Requirements for the development, validation and routine control of a sterilization process for medical devices (EN ISO 22441)	27 May 2028
35.	Small-bore connectors for liquids and gases in healthcare applications - Part 2: Connectors for respiratory applications (ISO/DIS 80369-2)	27 May 2024

36.	Medical electrical equipment - Part 2-55: Particular requirements for basic safety and essential performance of respiratory gas monitors (EN ISO 80601-2-55)	27 May 2028
37.	Medical electrical equipment - Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment (EN ISO 80601-2-61)	27 May 2028
38.	Medical electrical equipment - Part 2-67: Particular requirements for basic safety and essential performance of oxygen-conserving equipment (EN ISO 80601-2-67)	27 May 2028
39.	Medical electrical equipment - Part 2-70: Particular requirements for the basic safety and essential performance of sleep apnoea breathing therapy equipment (EN ISO 80601-2-70)	27 May 2028
40.	Medical electrical equipment - Part 2-72: Particular requirements for basic safety and essential performance of home healthcare environment ventilators for ventilator-dependent patients (EN ISO 80601-2-72)	27 May 2028
41.	Medical electrical equipment - Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment (EN ISO 80601-2-74)	27 May 2028
42.	Medical electrical equipment - Part 2-79: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory impairment (EN ISO 80601-2-79)	27 May 2028
43.	Medical electrical equipment - Part 2-80: Particular requirements for basic safety and essential performance of ventilatory support equipment for ventilatory insufficiency (EN ISO 80601-2-80)	27 May 2028
44.	Medical electrical equipment - Part 2-84: Particular requirements for the basic safety and essential performance of ventilators for the emergency medical services environment (prEN ISO 80601-2-84)	27 May 2028
45.	Medical electrical equipment - Part 2-85: Particular requirements for the basic safety and essential performance of cerebral tissue oximeter equipment (EN ISO 80601-2-85)	27 May 2028

46.	Medical electrical equipment - Part 2-86: Particular requirements for the basic safety and essential performance of electrocardiographs, including diagnostic equipment, monitoring equipment, ambulatory equipment, electrodes, cables and leadwires (IEC 80601-2-86)	27 May 2028
47.	Medical electrical equipment - Part 2-87: Particular requirements for basic safety and essential performance of high-frequency ventilators (EN ISO 80601-2-87)	27 May 2028
48.	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 2028
49.	Medical electrical equipment - Part 2-90: Particular requirements for basic safety and essential performance of respiratory high-flow therapy (EN ISO 80601-2-90)	27 May 2028
50.	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 2028
51.	Respiratory infection prevention devices for self- and third party protection - Requirements for different performance classes and test methods	27 May 2028

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 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 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 Graphical symbols - Safety colours and safety signs - Registered safety signs	27 May 2028
4.	EN ISO 11135 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 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 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose	27 May 2024
7.	EN ISO 11607-1 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 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	27 May 2024
9.	EN ISO 11737-1 Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products	27 May 2024
10.	EN ISO 11737-2 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 Aseptic processing of health care products - Part 1: General requirements	27 May 2024
12.	EN ISO 13408-2 Aseptic processing of health care products - Part 2: Filtration	27 May 2028
13.	EN ISO 13408-3 Aseptic processing of health care products - Part 3: Lyophilization	27 May 2028
14.	EN ISO 13408-4 Aseptic processing of health care products - Part 4: Clean-in-place technologies	27 May 2028
15.	EN ISO 13408-5 Aseptic processing of health care products - Part 5: Sterilization in place	27 May 2028
16.	EN ISO 13408-6 Aseptic processing of health care products - Part 6: Isolator systems	27 May 2024
17.	EN ISO 13408-7	27 May 2028

	Aseptic processing of health care products - Part 7: Alternative processes for medical devices and combination products	
18.	EN ISO 13485 Medical devices - Quality management systems - Requirements for regulatory purposes	27 May 2024
19.	EN 13532 General requirements for *in vitro* diagnostic medical devices for self-testing	27 May 2028
20.	EN 13612 Performance evaluation of *in vitro* diagnostic medical devices	27 May 2028
21.	EN 13641 Elimination or reduction of risk of infection related to *in vitro* diagnostic reagents	27 May 2028
22.	EN 13975 Sampling procedures used for acceptance testing of *in vitro* diagnostic medical devices - Statistical aspects	27 May 2028
23.	EN 14136 Use of external quality assessment schemes in the assessment of the performance of *in vitro* diagnostic examination procedures	27 May 2028
24.	EN ISO 14937 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 2028
25.	EN ISO 14971 Medical devices - Application of risk management to medical devices	27 May 2024
26.	EN ISO 15193 *In vitro* diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for content and presentation of reference	27 May 2028

	measurement procedures	
27.	EN ISO 15194 *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 2028
28.	EN ISO 15197 *In vitro* diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus	27 May 2028
29.	EN ISO 15223-1 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements	27 May 2024
30.	EN ISO 17511 *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 Sterilisation of medical devices - Information to be provided by the medical device manufacturer for the processing of medical devices	27 May 2024
32.	EN ISO 17665 Sterilization of health care products - Moist heat - Requirements for the development, validation and routine control of a sterilization process for medical devices	27 May 2024
33.	EN ISO 18113-1 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements	27 May 2028
34.	EN ISO 18113-2 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: *In*	27 May 2028

	vitro diagnostic reagents for professional use	
35.	EN ISO 18113-3 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: *In vitro* diagnostic instruments for professional use	27 May 2028
36.	EN ISO 18113-4 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 4: *In vitro* diagnostic reagents for self-testing	27 May 2028
37.	EN ISO 18113-5 *In vitro* diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 5: *In vitro* diagnostic instruments for self-testing	27 May 2028
38.	EN ISO 20857 Sterilization of health care products - Dry heat - Requirements for the development, validation and routine control of a sterilization process for medical devices	27 May 2028
39.	EN ISO 23640 *In vitro* diagnostic medical devices - Evaluation of stability of *in vitro* diagnostic reagents	27 May 2028
40.	EN ISO 25424 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 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements	27 May 2028
42.	EN 61326-2-6 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - *In vitro* diagnostic (IVD) medical equipment	27 May 2028

43.	EN 61010-2-101 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 2028
44.	EN 62304 Medical device software - Software life-cycle processes	27 May 2028
45.	EN 62366-1 Medical devices - Application of usability engineering to medical devices	27 May 2028

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

Reference information		**Deadline for the adoption**
1.	Sterilization of health care products - Microbiological methods - Part 3: Bacterial endotoxin testing (EN ISO 11737-3)	27 May 2028
2.	Sterilization of health care products - Radiation - Substantiation of selected sterilization dose: Method VDmaxSD (ISO 13004)	27 May 2028
3.	*In vitro* diagnostic medical devices - Clinical performance studies using specimens from human subjects - Good study practice (ISO 20916)	27 May 2028
4.	Sterilization of health care products - Low temperature vaporized hydrogen peroxide - Requirements for the development, validation and routine control of a sterilization process for medical devices (EN ISO 22441)	27 May 2028

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 Annex Z to that standard. 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.

A standard containing normative references to undated standards shall indicate the dated version of any such referenced standard in its Annex Z.

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) and Part 17: Establishment of allowable limits for leachable substances (EN ISO 10993-17)

In the standard EN ISO 10993-7, 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, 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)

The existing standard EN ISO 15223-1 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.

The revised standard shall include a specific symbol for the authorised representative in the Union, as "EU REP" instead of "EC REP", removing any reference to the term "European Community".

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)

The existing standard EN ISO 23908 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)

The existing standard EN 82304-1 shall be modified by ensuring a clear separation between products (software) that 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 the basis of that standard.