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Contents

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Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

II

(Non-legislative acts)

DECISIONS

COMMISSION IMPLEMENTING DECISION (EU) 2020/437

of 24 March 2020

on the harmonised standards for medical devices drafted in support of Council Directive 93/42/EEC

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(6) thereof,

Whereas:

(1) In accordance with Article 5(1) of Council Directive 93/42/EEC ([2]), Member States are to presume compliance with the essential requirements referred to in Article 3 of that Directive in respect of medical devices which are in conformity with the relevant national standards adopted pursuant to the harmonized standards the references of which have been published in the *Official Journal of the European Union*.

(2) By letters BC/CEN/CENELEC/09/89 of 19 December 1991, M/023 - BC/CEN/03/023/93-08 of 5 August 1993 and M/295 of 9 September 1999, the Commission made requests to the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (Cenelec) for the drafting of new harmonised standards and the revision of existing harmonised standards in support of Directive 93/42/EEC.

(3) On the basis of the request M/295 of 9 September 1999, CEN revised the harmonised standards EN ISO 10993-11:2009, EN 14683:2005 and EN ISO 15747:2011, the references of which have been published in the *Official Journal of the European Union* ([3]), in order to include the latest technical and scientific progress. This resulted in the adoption of the harmonised standards EN ISO 10993-11:2018, EN 14683:2019+AC:2019 and EN ISO 15747:2019.

(4) The Commission together with CEN has assessed whether standards EN ISO 10993-11:2018, EN 14683:2019 +AC:2019 and EN ISO 15747:2019 comply with the request.

(5) The harmonised standards EN ISO 10993-11:2018, EN 14683:2019+AC:2019 and EN ISO 15747:2019 satisfy the requirements which they aim to cover and which are set out in Directive 93/42/EEC. It is therefore appropriate to publish the references of those standards in the *Official Journal of the European Union*.

(6) The harmonised standards EN ISO 10993-11:2018, EN 14683:2019+AC:2019 and EN ISO 15747:2019 replace the harmonised standards EN ISO 10993-11:2009, EN 14683:2005 and EN ISO 15747:2011 respectively. It is therefore necessary to withdraw the references of standards EN ISO 10993-11:2009, EN 14683:2005 and EN ISO 15747:2011 from the *Official Journal of the European Union*.

([1]) OJ L 316, 14.11.2012, p. 12.
([2]) Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ L 169, 12.7.1993, p. 1).
([3]) OJ C 389, 17.11.2017, p. 29.

(7) On the basis of the request BC/CEN/CENELEC/09/89 of 19 December 1991, CEN revised the harmonised standards EN ISO 11137-1:2015, EN ISO 13408-2:2011 and EN ISO 13485:2016, the references of which have been published in the *Official Journal of the European Union* ([4]), in order to include the latest technical and scientific progress. This resulted in the adoption of the harmonised standards EN ISO 11137-1:2015/A2:2019 and EN ISO 13408-2:2018 and the corrigendum EN ISO 13485:2016/AC:2018.

(8) The Commission together with CEN has assessed whether standards EN ISO 11137-1:2015/A2:2019 and EN ISO 13408-2:2018 and the corrigendum EN ISO 13485:2016/AC:2018 comply with the request.

(9) The harmonised standards EN ISO 11137-1:2015/A2:2019 and EN ISO 13408-2:2018 and the corrigendum EN ISO 13485:2016/AC:2018 satisfy the requirements which they aim to cover and which are set out in Directive 93/42/EEC. It is therefore appropriate to publish the references of those standards and of the corrigendum in the *Official Journal of the European Union*.

(10) The harmonised standard EN ISO 13408-2:2018 and the corrigendum EN ISO 13485:2016/AC:2018 replace the harmonised standard EN ISO 13408-2:2011 and the corrigendum EN ISO 13485:2016/AC:2016 respectively. It is therefore necessary to withdraw the reference of standard EN ISO 13408-2:2011 and of corrigendum EN ISO 13485:2016/AC:2016 from the *Official Journal of the European Union*.

(11) On the basis of the request M/023 - BC/CEN/03/023/93-08 of 5 August 1993, CEN revised the harmonised standards EN ISO 11990-1:2004, EN ISO 11990-2:2004, EN 13976-2:2011, EN ISO 15883-4:2009, EN ISO 17664:2004 and EN ISO 21987:2009, the references of which have been published in the *Official Journal of the European Union* ([5]), in order to include the latest technical and scientific progress. This resulted in the adoption of the harmonised standards EN ISO 11990:2018, EN 13976-2:2018, EN ISO 15883-4:2018, EN ISO 17664:2017 and EN ISO 21987:2017.

(12) The Commission together with CEN has assessed whether standards EN ISO 11990:2018, EN 13976-2:2018, EN ISO 15883-4:2018, EN ISO 17664:2017 and EN ISO 21987:2017 comply with the request.

(13) The harmonised standards EN ISO 11990:2018, EN 13976-2:2018, EN ISO 15883-4:2018, EN ISO 17664:2017 and EN ISO 21987:2017 satisfy the requirements which they aim to cover and which are set out in Directive 93/42/EEC. It is therefore appropriate to publish the references of those standards in the *Official Journal of the European Union*.

(14) The harmonised standards EN ISO 11990:2018, EN 13976-2:2018, EN ISO 15883-4:2018, EN ISO 17664:2017 and EN ISO 21987:2017 replace the harmonised standards EN ISO 11990-1:2004, EN ISO 11990-2:2004, EN 13976-2:2011, EN ISO 15883-4:2009, EN ISO 17664:2004 and EN ISO 21987:2009 respectively. It is therefore necessary to withdraw the references of standards EN ISO 11990-1:2004, EN ISO 11990-2:2004, EN 13976-2:2011, EN ISO 15883-4:2009, EN ISO 17664:2004 and EN ISO 21987:2009 from the *Official Journal of the European Union*.

(15) On the basis of the request M/295 of 9 September 1999, CEN drafted the new harmonised standards EN 11608-7:2017, EN 13795-1:2019, EN 13795-2:2019 and EN ISO 81060-2:2019. The Commission together with CEN has assessed whether those standards comply with the request.

(16) The harmonised standards EN 11608-7:2017, EN 13795-1:2019, EN 13795-2:2019 and EN ISO 81060-2:2019 satisfy the requirements which they aim to cover and which are set out in Directive 93/42/EEC. It is therefore appropriate to publish the references of those standards in the *Official Journal of the European Union*.

(17) On the basis of the request BC/CEN/CENELEC/09/89 of 19 December 1991, CEN drafted the new harmonised standard EN ISO 25424:2019. The Commission together with CEN has assessed whether that standard complies with the request.

(18) The harmonised standard EN ISO 25424:2019 satisfies the requirements, which it aims to cover and which are set out in Directive 93/42/EEC. It is therefore appropriate to publish the reference of that standard in the *Official Journal of the European Union*.

([4]) OJ C 389, 17.11.2017, p. 29.
([5]) OJ C 389, 17.11.2017, p. 29.

(19) In order to give manufacturers sufficient time to adapt their products to the revised specifications in standards and the corrigendum published by this Decision, it is necessary to defer the withdrawal of the reference of the standards and the corrigendum that are replaced.

(20) In the interests of clarity and legal certainty, a complete list of references of harmonised standards drafted in support of Directive 93/42/EEC and satisfying the essential requirements they aim to cover should be published in one act. The other references of standards published in the Commission communication 2017/C 389/03 ([6]) should therefore also be included in this Decision. That Communication should therefore be repealed from the date of entry into force of this Decision. However, it should continue to apply in respect of the references of the standards that are withdrawn by this Decision, given that it is necessary to defer withdrawal of those references.

(21) In accordance with the second subparagraph of Article 120(2) of Regulation (EU) 2017/745 of the European Parliament and of the Council ([7]), certificates issued by notified bodies in accordance with Directive 93/42/EEC from 25 May 2017 are to remain valid until the end of the period indicated on the certificate, which is not to exceed five years from its issuance. They are to however become void at the latest on 27 May 2024. In accordance with the first subparagraph of Article 120(3) of Regulation (EU) 2017/745 a device which is a class I device pursuant to Directive 93/42/EEC, for which the declaration of conformity was drawn up prior to 26 May 2020 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body, or which has a certificate that was issued in accordance with Directive 93/42/EEC and that is valid by virtue of Article 120(2), may be placed on the market or put into service until 26 May 2024, provided that from 26 May 2020 it continues to comply with Directive 93/42/EEC, and provided there are no significant changes in the design and intended purpose. This Decision should therefore apply only until 26 May 2024.

(22) The requirements for medical devices laid down in Directive 93/42/EEC are different from those laid down in Regulation (EU) 2017/745. The standards drafted in support of Directive 93/42/EEC should therefore not be used to demonstrate conformity with requirements of Regulation (EU) 2017/745.

(23) Compliance with a harmonised standard confers a presumption of conformity with the corresponding essential requirements set out in Union harmonisation legislation from the date of publication of the reference of such standard in the *Official Journal of the European Union*. This Decision should therefore enter into force on the date of its publication,

HAS ADOPTED THIS DECISION:

Article 1

The references of the harmonised standards for medical devices drafted in support of Directive 93/42/EEC and listed in Annex I to this Decision are hereby published in the *Official Journal of the European Union*.

Article 2

Commission communication 2017/C 389/03 is repealed. It shall continue to apply until 30 September 2021 in respect of the references of the standards listed in Annex II to this Decision.

Article 3

The harmonised standards for medical devices drafted in support of Directive 93/42/EEC and listed in Annexes I and II to this Decision may not be used to confer presumption of conformity with the requirements of Regulation (EU) 2017/745.

([6]) Commission communication in the framework of the implementation of Council Directive 93/42/EEC concerning medical devices (2017/C 389/03) (OJ C 389, 17.11.2017, p. 29).

([7]) 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).

Article 4

This Decision shall enter into force on the day of its publication in the *Official Journal of the European Union*.

It shall apply until 26 May 2024.

Done at Brussels, 24 March 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

No	Reference of the standard
1.	EN 285:2006+A2:2009 Sterilization - Steam sterilizers - Large sterilizers
2.	EN 455-1:2000 Medical gloves for single use - Part 1: Requirements and testing for freedom from holes
3.	EN 455-2:2009+A2:2013 Medical gloves for single use - Part 2: Requirements and testing for physical properties
4.	EN 455-3:2006 Medical gloves for single use - Part 3: Requirements and testing for biological evaluation
5.	EN 455-4:2009 Medical gloves for single use - Part 4: Requirements and testing for shelf life determination
6.	EN 556-1:2001 Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices EN 556-1:2001/AC:2006
7.	EN 556-2:2015 Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 2: Requirements for aseptically processed medical devices
8.	EN 794-3:1998+A2:2009 Lung ventilators - Part 3: Particular requirements for emergency and transport ventilators
9.	EN 1041:2008 Information supplied by the manufacturer of medical devices
10.	EN 1060-3:1997+A2:2009 Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems
11.	EN 1060-4:2004 Non-invasive sphygmomanometers - Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers
12.	EN ISO 1135-4:2011 Transfusion equipment for medical use - Part 4: Transfusion sets for single use (ISO 1135-4:2010)
13.	EN 1282-2:2005+A1:2009 Tracheostomy tubes - Part 2: Paediatric tubes (ISO 5366-3:2001, modified)
14.	EN 1422:1997+A1:2009 Sterilizers for medical purposes - Ethylene oxide sterilizers - Requirements and test methods
15.	EN 1618:1997 Catheters other than intravascular catheters - Test methods for common properties
16.	EN 1639:2009 Dentistry - Medical devices for dentistry - Instruments
17.	EN 1640:2009 Dentistry - Medical devices for dentistry - Equipment
18.	EN 1641:2009 Dentistry - Medical devices for dentistry - Materials
19.	EN 1642:2011 Dentistry - Medical devices for dentistry - Dental implants

No	Reference of the standard
20.	EN 1707:1996 Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment - Lock fittings
21.	EN 1782:1998+A1:2009 Tracheal tubes and connectors
22.	EN 1789:2007+A1:2010 Medical vehicles and their equipment - Road ambulances
23.	EN 1820:2005+A1:2009 Anaesthetic reservoir bags (ISO 5362:2000, modified)
24.	EN 1865-1:2010+A1:2015 Patient handling equipment used in road ambulances - Part 1: General stretcher systems and patient handling equipment
25.	EN 1865-2:2010+A1:2015 Patient handling equipment used in road ambulances - Part 2: Power assisted stretcher
26.	EN 1865-3:2012 Patient handling equipment used in road ambulances - Part 3: Heavy duty stretcher
27.	EN 1865-4:2012 Patient handling equipment used in road ambulances - Part 4: Foldable patient transfer chair
28.	EN 1865-5:2012 Patient handling equipment used in road ambulances - Part 5: Stretcher support
29.	EN 1985:1998 Walking aids - General requirements and test methods Notice: This standard still needs to be amended to take into account the requirements introduced by Directive 2007/47/EC. The amended standard will be published by CEN as soon as possible. Manufacturers are advised to check whether all relevant essential requirements of the amended directive are appropriately covered.
30.	EN ISO 3826-2:2008 Plastics collapsible containers for human blood and blood components - Part 2: Graphical symbols for use on labels and instruction leaflets (ISO 3826-2:2008)
31.	EN ISO 3826-3:2007 Plastics collapsible containers for human blood and blood components - Part 3: Blood bag systems with integrated features (ISO 3826- 3:2006)
32.	EN ISO 3826-4:2015 Plastics collapsible containers for human blood and blood components - Part 4: Aphaeresis blood bag systems with integrated features (ISO 3826-4:2015)
33.	EN ISO 4074:2002 Natural latex rubber condoms - Requirements and test methods (ISO 4074:2002)
34.	EN ISO 4135:2001 Anaesthetic and respiratory equipment - Vocabulary (ISO 4135:2001)
35.	EN ISO 5359:2008 Low-pressure hose assemblies for use with medical gases (ISO 5359:2008) EN ISO 5359:2008/A1:2011
36.	EN ISO 5360:2009 Anaesthetic vaporizers - Agent-specific filling systems (ISO 5360:2006)
37.	EN ISO 5366-1:2009 Anaesthetic and respiratory equipment - Tracheostomy tubes - Part 1: Tubes and connectors for use in adults (ISO 5366-1:2000)
38.	EN ISO 5840:2009 Cardiovascular implants - Cardiac valve prostheses (ISO 5840:2005)

No	Reference of the standard
39.	EN ISO 7197:2009 Neurosurgical implants - Sterile, single-use hydrocephalus shunts and components (ISO 7197:2006, including Cor 1:2007)
40.	EN ISO 7376:2009 Anaesthetic and respiratory equipment - Laryngoscopes for tracheal intubation (ISO 7376:2009)
41.	EN ISO 7396-1:2007 Medical gas pipeline systems - Part 1: Pipeline systems for compressed medical gases and vacuum (ISO 7396-1:2007) EN ISO 7396-1:2007/A1:2010 EN ISO 7396-1:2007/A2:2010
42.	EN ISO 7396-2:2007 Medical gas pipeline systems - Part 2: Anaesthetic gas scavenging disposal systems (ISO 7396-2:2007)
43.	EN ISO 7886-3:2009 Sterile hypodermic syringes for single use - Part 3: Auto-disable syringes for fixed-dose immunization (ISO 7886-3:2005)
44.	EN ISO 7886-4:2009 Sterile hypodermic syringes for single use - Part 4: Syringes with reuse prevention feature (ISO 7886-4:2006)
45.	EN ISO 8185:2009 Respiratory tract humidifiers for medical use - Particular requirements for respiratory humidification systems (ISO 8185:2007)
46.	EN ISO 8359:2009 Oxygen concentrators for medical use - Safety requirements (ISO 8359:1996) EN ISO 8359:2009/A1:2012
47.	EN ISO 8835-2:2009 Inhalational anaesthesia systems - Part 2: Anaesthetic breathing systems (ISO 8835- 2:2007)
48.	EN ISO 8835-3:2009 Inhalational anaesthesia systems - Part 3: Transfer and receiving systems of active anaesthetic gas scavenging systems (ISO 8835-3:2007) EN ISO 8835-3:2009/A1:2010
49.	EN ISO 8835-4:2009 Inhalational anaesthesia systems - Part 4: Anaesthetic vapour delivery devices (ISO 8835- 4:2004)
50.	EN ISO 8835-5:2009 Inhalational anaesthesia systems - Part 5: Anaesthetic ventilators (ISO 8835-5:2004)
51.	EN ISO 9170-1:2008 Terminal units for medical gas pipeline systems - Part 1: Terminal units for use with compressed medical gases and vacuum (ISO 9170-1:2008)
52.	EN ISO 9170-2:2008 Terminal units for medical gas pipeline systems - Part 2: Terminal units for anaesthetic gas scavenging systems (ISO 9170-2:2008)
53.	EN ISO 9360-1:2009 Anaesthetic and respiratory equipment - Heat and moisture exchangers (HMEs) for humidifying respired gases in humans - Part 1: HMEs for use with minimum tidal volumes of 250 ml (ISO 9360-1:2000)
54.	EN ISO 9360-2:2009 Anaesthetic and respiratory equipment - Heat and moisture exchangers (HMEs) for humidifying respired gases in humans - Part 2: HMEs for use with tracheostomized patients having minimum tidal volumes of 250 ml (ISO 9360-2:2001)

No	Reference of the standard
55.	EN ISO 9713:2009 Neurosurgical implants - Self-closing intracranial aneurysm clips (ISO 9713:2002)
56.	EN ISO 10079-1:2009 Medical suction equipment - Part 1: Electrically powered suction equipment - Safety requirements (ISO 10079-1:1999)
57.	EN ISO 10079-2:2009 Medical suction equipment - Part 2: Manually powered suction equipment (ISO 10079-2:1999)
58.	EN ISO 10079-3:2009 Medical suction equipment - Part 3: Suction equipment powered from a vacuum or pressure source (ISO 10079-3:1999)
59.	EN ISO 10328:2016 Prosthetics - Structural testing of lower-limb prostheses - Requirements and test methods (ISO 10328:2016)
60.	EN ISO 10524-1:2006 Pressure regulators for use with medical gases - Part 1: Pressure regulators and pressure regulators with flow-metering devices (ISO 10524- 1:2006)
61.	EN ISO 10524-2:2006 Pressure regulators for use with medical gases - Part 2: Manifold and line pressure regulators (ISO 10524-2:2005)
62.	EN ISO 10524-3:2006 Pressure regulators for use with medical gases - Part 3: Pressure regulators integrated with cylinder valves (ISO 10524-3:2005)
63.	EN ISO 10524-4:2008 Pressure regulators for use with medical gases - Part 4: Low-pressure regulators (ISO 10524- 4:2008)
64.	EN ISO 10535:2006 Hoists for the transfer of disabled persons - Requirements and test methods (ISO 10535:2006) Notice: This standard still needs to be amended to take into account the requirements introduced by Directive 2007/47/EC. The amended standard will be published by CEN as soon as possible. Manufacturers are advised to check whether all relevant essential requirements of the amended directive are appropriately covered.
65.	EN ISO 10555-1:2009 Sterile, single-use intravascular catheters - Part 1: General requirements (ISO 10555-1:1995, including Amd 1:1999 and Amd 2:2004)
66.	EN ISO 10651-2:2009 Lung ventilators for medical use - Particular requirements for basic safety and essential performance - Part 2: Home care ventilators for ventilator-dependent patients (ISO 10651- 2:2004)
67.	EN ISO 10651-4:2009 Lung ventilators - Part 4: Particular requirements for operator-powered resuscitators (ISO 10651-4:2002)
68.	EN ISO 10651-6:2009 Lung ventilators for medical use - Particular requirements for basic safety and essential performance - Part 6: Home-care ventilatory support devices (ISO 10651-6:2004)
69.	EN ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009) EN ISO 10993-1:2009/AC:2010
70.	EN ISO 10993-3:2014 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2014)

No	Reference of the standard
71.	EN ISO 10993-4:2009 Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood (ISO 10993-4:2002, including Amd 1:2006)
72.	EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
73.	EN ISO 10993-6:2009 Biological evaluation of medical devices - Part 6: Tests for local effects after implantation (ISO 10993-6:2007)
74.	EN ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (ISO 10993-7:2008) EN ISO 10993-7:2008/AC:2009
75.	EN ISO 10993-9:2009 Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products (ISO 10993-9:2009)
76.	EN ISO 10993-11:2018 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017)
77.	EN ISO 10993-12:2012 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2012)
78.	EN ISO 10993-13:2010 Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices (ISO 10993-13:2010)
79.	EN ISO 10993-14:2009 Biological evaluation of medical devices - Part 14: Identification and quantification of degradation products from ceramics (ISO 10993-14:2001)
80.	EN ISO 10993-15:2009 Biological evaluation of medical devices - Part 15: Identification and quantification of degradation products from metals and alloys (ISO 10993-15:2000)
81.	EN ISO 10993-16:2010 Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables (ISO 10993-16:2010)
82.	EN ISO 10993-17:2009 Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances (ISO 10993-17:2002)
83.	EN ISO 10993-18:2009 Biological evaluation of medical devices - Part 18: Chemical characterization of materials (ISO 10993-18:2005)
84.	EN ISO 11135-1:2007 Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11135-1:2007)
85.	EN ISO 11137-1:2015 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006, including Amd 1:2013) EN ISO 11137-1:2015/A2:2019
86.	EN ISO 11137-2:2015 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:2013)

No	Reference of the standard
87.	EN ISO 11138-2:2009 Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138-2:2006)
88.	EN ISO 11138-3:2009 Sterilization of health care products - Biological indicators - Part 3: Biological indicators for moist heat sterilization processes (ISO 11138-3:2006)
89.	EN ISO 11140-1:2009 Sterilization of health care products - Chemical indicators - Part 1: General requirements (ISO 11140-1:2005)
90.	EN ISO 11140-3:2009 Sterilization of health care products - Chemical indicators - Part 3: Class 2 indicator systems for use in the Bowie and Dick-type steam penetration test (ISO 11140-3:2007, including Cor 1:2007)
91.	EN ISO 11197:2009 Medical supply units (ISO 11197:2004)
92.	EN ISO 11607-1:2009 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006)
93.	EN ISO 11607-2:2006 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2006)
94.	EN ISO 11608-7:2017 Needle-based injection systems for medical use - Requirements and test methods - Part 7: Accessibility for persons with visual impairment (ISO 11608-7:2016)
95.	EN ISO 11737-1:2006 Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2006) EN ISO 11737-1:2006/AC:2009
96.	EN ISO 11737-2:2009 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2009)
97.	EN ISO 11810-1:2009 Lasers and laser-related equipment - Test method and classification for the laser resistance of surgical drapes and/or patient protective covers - Part 1: Primary ignition and penetration (ISO 11810-1:2005)
98.	EN ISO 11810-2:2009 Lasers and laser-related equipment - Test method and classification for the laser-resistance of surgical drapes and/or patient-protective covers - Part 2: Secondary ignition (ISO 11810-2:2007)
99.	EN ISO 11979-8:2009 Ophthalmic implants - Intraocular lenses - Part 8: Fundamental requirements (ISO 11979- 8:2006)
100.	EN ISO 11990:2018 Lasers and laser-related equipment - Determination of laser resistance of tracheal tube shaft and tracheal cuffs (ISO 11990:2018)
101.	EN 12006-2:1998+A1:2009 Non active surgical implants - Particular requirements for cardiac and vascular implants - Part 2: Vascular prostheses including cardiac valve conduits

No	Reference of the standard
102.	EN 12006-3:1998+A1:2009 Non active surgical implants - Particular requirements for cardiac and vascular implants - Part 3: Endovascular devices
103.	EN 12183:2009 Manual wheelchairs - Requirements and test methods
104.	EN 12184:2009 Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods
105.	EN 12342:1998+A1:2009 Breathing tubes intended for use with anaesthetic apparatus and ventilators
106.	EN 12470-1:2000+A1:2009 Clinical thermometers - Part 1: Metallic liquid- in-glass thermometers with maximum device
107.	EN 12470-2:2000+A1:2009 Clinical thermometers - Part 2: Phase change type (dot matrix) thermometers
108.	EN 12470-3:2000+A1:2009 Clinical thermometers - Part 3: Performance of compact electrical thermometers (non-predictive and predictive) with maximum device
109.	EN 12470-4:2000+A1:2009 Clinical thermometers - Part 4: Performance of electrical thermometers for continuous measurement
110.	EN 12470-5:2003 Clinical thermometers - Part 5: Performance of infra-red ear thermometers (with maximum device) Notice: This standard still needs to be amended to take into account the requirements introduced by Directive 2007/47/EC. The amended standard will be published by CEN as soon as possible. Manufacturers are advised to check whether all relevant essential requirements of the amended directive are appropriately covered.
111.	EN ISO 12870:2009 Ophthalmic optics - Spectacle frames - Requirements and test methods (ISO 12870:2004)
112.	EN 13060:2014 Small steam sterilizers
113.	EN ISO 13408-1:2015 Aseptic processing of health care products - Part 1: General requirements (ISO 13408-1:2008, including Amd 1:2013)
114.	EN ISO 13408-2:2018 Aseptic processing of health care products - Part 2: Sterilizing filtration (ISO 13408-2:2018)
115.	EN ISO 13408-3:2011 Aseptic processing of health care products - Part 3: Lyophilization (ISO 13408-3:2006)
116.	EN ISO 13408-4:2011 Aseptic processing of health care products - Part 4: Clean-in-place technologies (ISO 13408-4:2005)
117.	EN ISO 13408-5:2011 Aseptic processing of health care products - Part 5: Sterilization in place (ISO 13408-5:2006)

No	Reference of the standard
118.	EN ISO 13408-6:2011 Aseptic processing of health care products - Part 6: Isolator systems (ISO 13408-6:2005)
119.	EN ISO 13408-7:2015 Aseptic processing of health care products - Part 7: Alternative processes for medical devices and combination products (ISO 13408-7:2012)
120.	EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) EN ISO 13485:2016/AC:2018
121.	EN 13544-1:2007+A1:2009 Respiratory therapy equipment - Part 1: Nebulizing systems and their component
122.	EN 13544-2:2002+A1:2009 Respiratory therapy equipment - Part 2: Tubing and connectors
123.	EN 13544-3:2001+A1:2009 Respiratory therapy equipment - Part 3: Air entrainment devices
124.	EN 13624:2003 Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of fungicidal activity of chemical disinfectants for instruments used in the medical area - Test method and requirements (phase 2, step 1)
125.	EN 13718-1:2008 Medical vehicles and their equipment - Air ambulances - Part 1: Requirements for medical devices used in air ambulances
126.	EN 13718-2:2015 Medical vehicles and their equipment - Air ambulances - Part 2: Operational and technical requirements for air ambulances
127.	EN 13726-1:2002 Test methods for primary wound dressings - Part 1: Aspects of absorbency EN 13726-1:2002/AC:2003
128.	EN 13726-2:2002 Test methods for primary wound dressings - Part 2: Moisture vapour transmission rate of permeable film dressings
129.	EN 13727:2012 Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of bactericidal activity in the medical area - Test method and requirements (phase 2, step 1)
130.	EN 13795-1:2019 Surgical clothing and drapes - Requirements and test methods - Part 1: Surgical drapes and gowns
131.	EN 13795-2:2019 Surgical clothing and drapes - Requirements and test methods - Part 2: Clean air suits
132.	EN 13867:2002+A1:2009 Concentrates for haemodialysis and related therapies
133.	EN 13976-1:2011 Rescue systems - Transportation of incubators - Part 1: Interface conditions

No	Reference of the standard
134.	EN 13976-2:2018 Rescue systems - Transportation of incubators - Part 2: System requirements
135.	EN 14079:2003 Non-active medical devices - Performance requirements and test methods for absorbent cotton gauze and absorbent cotton and viscose gauze
136.	EN 14139:2010 Ophthalmic optics - Specifications for ready-to- wear spectacles
137.	EN ISO 14155:2011 Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2011) EN ISO 14155:2011/AC:2011
138.	EN 14180:2003+A2:2009 Sterilizers for medical purposes - Low temperature steam and formaldehyde sterilizers - Requirements and testing
139.	EN 14348:2005 Chemical disinfectants and antiseptics - Quantitative suspension test for the evaluation of mycobactericidal activity of chemical disinfectants in the medical area including instrument disinfectants - Test methods and requirements (phase 2, step 1)
140.	EN ISO 14408:2009 Tracheal tubes designed for laser surgery - Requirements for marking and accompanying information (ISO 14408:2005)
141.	EN 14561:2006 Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of bactericidal activity for instruments used in the medical area - Test method and requirements (phase 2, step 2)
142.	EN 14562:2006 Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of fungicidal or yeasticidal activity for instruments used in the medical area - Test method and requirements (phase 2, step 2)
143.	EN 14563:2008 Chemical disinfectants and antiseptics - Quantitative carrier test for the evaluation of mycobactericidal or tuberculocidal activity of chemical disinfectants used for instruments in the medical area - Test method and requirements (phase 2, step 2)
144.	EN ISO 14602:2011 Non-active surgical implants - Implants for osteosynthesis - Particular requirements (ISO 14602:2010)
145.	EN ISO 14607:2009 Non-active surgical implants - Mammary implants - Particular requirements (ISO 14607:2007)
146.	EN ISO 14630:2009 Non-active surgical implants - General requirements (ISO 14630:2008)
147.	EN 14683:2019+AC:2019 Medical face masks - Requirements and test methods
148.	EN ISO 14889:2009 Ophthalmic optics - Spectacle lenses - Fundamental requirements for uncut finished lenses (ISO 14889:2003)
149.	EN 14931:2006 Pressure vessels for human occupancy (PVHO) - Multi-place pressure chamber systems for hyperbaric therapy - Performance, safety requirements and testing

No	Reference of the standard
150.	EN ISO 14937:2009 Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices (ISO 14937:2009)
151.	EN ISO 14971:2012 Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
152.	EN ISO 15001:2011 Anaesthetic and respiratory equipment - Compatibility with oxygen (ISO 15001:2010)
153.	EN ISO 15002:2008 Flow-metering devices for connection to terminal units of medical gas pipeline systems (ISO 15002:2008)
154.	EN ISO 15004-1:2009 Ophthalmic instruments - Fundamental requirements and test methods - Part 1: General requirements applicable to all ophthalmic instruments (ISO 15004-1:2006)
155.	EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)
156.	EN ISO 15747:2019 Plastic containers for intravenous injections (ISO 15747:2018)
157.	EN ISO 15798:2010 Ophthalmic implants - Ophthalmic viscosurgical devices (ISO 15798:2010)
158.	EN ISO 15883-1:2009 Washer-disinfectors - Part 1: General requirements, terms and definitions and tests (ISO 15883-1:2006)
159.	EN ISO 15883-2:2009 Washer-disinfectors - Part 2: Requirements and tests for washer-disinfectors employing thermal disinfection for surgical instruments, anaesthetic equipment, bowls, dishes, receivers, utensils, glassware, etc. (ISO 15883-2:2006)
160.	EN ISO 15883-3:2009 Washer-disinfectors - Part 3: Requirements and tests for washer-disinfectors employing thermal disinfection for human waste containers (ISO 15883-3:2006)
161.	EN ISO 15883-4:2018 Washer-disinfectors - Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes (ISO 15883-4:2018)
162.	EN 15986:2011 Symbol for use in the labelling of medical devices - Requirements for labelling of medical devices containing phthalate
163.	EN ISO 16061:2009 Instrumentation for use in association with non- active surgical implants - General requirements (ISO 16061:2008, Corrected version 2009-03- 15)
164.	EN ISO 16201:2006 Technical aids for disabled persons - Environmental control systems for daily living (ISO 16201:2006)
165.	EN ISO 17510-1:2009 Sleep apnoea breathing therapy - Part 1: Sleep apnoea breathing therapy equipment (ISO 17510-1:2007)

No	Reference of the standard
166.	EN ISO 17510-2:2009 Sleep apnoea breathing therapy - Part 2: Masks and application accessories (ISO 17510-2:2007)
167.	EN ISO 17664:2017 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices (ISO 17664:2017)
168.	EN ISO 17665-1:2006 Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665-1:2006)
169.	EN ISO 18777:2009 Transportable liquid oxygen systems for medical use - Particular requirements (ISO 18777:2005)
170.	EN ISO 18778:2009 Respiratory equipment - Infant monitors - Particular requirements (ISO 18778:2005)
171.	EN ISO 18779:2005 Medical devices for conserving oxygen and oxygen mixtures - Particular requirements (ISO 18779:2005)
172.	EN ISO 19054:2006 Rail systems for supporting medical equipment (ISO 19054:2005)
173.	EN 20594-1:1993 Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements (ISO 594-1:1986) EN 20594-1:1993/A1:1997 EN 20594-1:1993/AC:1996
174.	EN ISO 21534:2009 Non-active surgical implants - Joint replacement implants - Particular requirements (ISO 21534:2007)
175.	EN ISO 21535:2009 Non-active surgical implants - Joint replacement implants - Specific requirements for hip- joint replacement implants (ISO 21535:2007)
176.	EN ISO 21536:2009 Non-active surgical implants - Joint replacement implants - Specific requirements for knee- joint replacement implants (ISO 21536:2007)
177.	EN ISO 21649:2009 Needle-free injectors for medical use - Requirements and test methods (ISO 21649:2006)
178.	EN ISO 21969:2009 High-pressure flexible connections for use with medical gas systems (ISO 21969:2009)
179.	EN ISO 21987:2017 Ophthalmic optics - Mounted spectacle lenses (ISO 21987:2017)
180.	EN ISO 22442-1:2007 Medical devices utilizing animal tissues and their derivatives - Part 1: Application of risk management (ISO 22442-1:2007)
181.	EN ISO 22442-2:2007 Medical devices utilizing animal tissues and their derivatives - Part 2: Controls on sourcing, collection and handling (ISO 22442-2:2007)

No	Reference of the standard
182.	EN ISO 22442-3:2007 Medical devices utilizing animal tissues and their derivatives - Part 3: Validation of the elimination and/or inactivation of viruses and transmissible spongiform encephalopathy (TSE) agents (ISO 22442-3:2007)
183.	EN ISO 22523:2006 External limb prostheses and external orthoses - Requirements and test methods (ISO 22523:2006) Notice: This standard still needs to be amended to take into account the requirements introduced by Directive 2007/47/EC. The amended standard will be published by CEN as soon as possible. Manufacturers are advised to check whether all relevant essential requirements of the amended directive are appropriately covered.
184.	EN ISO 22675:2016 Prosthetics - Testing of ankle-foot devices and foot units - Requirements and test methods (ISO 22675:2016)
185.	EN ISO 23328-1:2008 Breathing system filters for anaesthetic and respiratory use - Part 1: Salt test method to assess filtration performance (ISO 23328- 1:2003)
186.	EN ISO 23328-2:2009 Breathing system filters for anaesthetic and respiratory use - Part 2: Non-filtration aspects (ISO 23328-2:2002)
187.	EN ISO 23747:2009 Anaesthetic and respiratory equipment - Peak expiratory flow meters for the assessment of pulmonary function in spontaneously breathing humans (ISO 23747:2007)
188.	EN ISO 25424:2019 Sterilization of health care products - Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 25424:2018)
189.	EN ISO 25539-1:2009 Cardiovascular implants - Endovascular devices - Part 1: Endovascular prostheses (ISO 25539-1:2003 including Amd 1:2005) EN ISO 25539-1:2009/AC:2011
190.	EN ISO 25539-2:2009 Cardiovascular implants - Endovascular devices - Part 2: Vascular stents (ISO 25539- 2:2008) EN ISO 25539-2:2009/AC:2011
191.	EN ISO 26782:2009 Anaesthetic and respiratory equipment - Spirometers intended for the measurement of time forced expired volumes in humans (ISO 26782:2009) EN ISO 26782:2009/AC:2009
192.	EN 27740:1992 Instruments for surgery, scalpels with detachable blades, fitting dimensions (ISO 7740:1985) EN 27740:1992/A1:1997 EN 27740:1992/AC:1996
193.	EN 60118-13:2005 Electroacoustics - Hearing aids - Part 13: Electromagnetic compatibility (EMC) (IEC 60118-13:2004) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
194.	EN 60522:1999 Determination of the permanent filtration of X- ray tube assemblies (IEC 60522:1999) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

No	Reference of the standard
195.	EN 60580:2000 Medical electrical equipment - Dose area product meters (IEC 60580:2000) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
196.	EN 60601-1:2006 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005) EN 60601-1:2006/AC:2010 EN 60601-1:2006/A1:2013 (IEC 60601-1:2005/A1:2012)
197.	EN 60601-1-1:2001 Medical electrical equipment - Part 1-1: General requirements for safety - Collateral standard: Safety requirements for medical electrical systems (IEC 60601-1-1:2000) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
198.	EN 60601-1-2:2015 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests (IEC 60601-1-2:2014)
199.	EN 60601-1-3:2008 Medical electrical equipment - Part 1-3: General requirements for basic safety and essential performance - Collateral Standard: Radiation protection in diagnostic X-ray equipment (IEC 60601-1-3:2008) EN 60601-1-3:2008/AC:2010 EN 60601-1-3:2008/A11:2016 Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
200.	EN 60601-1-4:1996 Medical electrical equipment - Part 1-4: General requirements for safety - Collateral standard: Programmable electrical medical systems (IEC 60601-1-4:1996) EN 60601-1-4:1996/A1:1999 (IEC 60601-1-4:1996/A1:1999) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
201.	EN 60601-1-6:2010 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability (IEC 60601-1-6:2010) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
202.	EN 60601-1-8:2007 Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems (IEC 60601-1-8:2006) EN 60601-1-8:2007/AC:2010 EN 60601-1-8:2007/A11:2017 Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
203.	EN 60601-1-10:2008 Medical electrical equipment - Part 1-10: General requirements for basic safety and essential performance - Collateral Standard: Requirements for the development of physiologic closed-loop controllers (IEC 60601-1-10:2007) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
204.	EN 60601-1-11:2010 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment (IEC 60601-1-11:2010) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

No	Reference of the standard
205.	EN 60601-2-1:1998 Medical electrical equipment - Part 2-1: Particular requirements for the safety of electron accelerators in the range of 1 MeV to 50 MeV (IEC 60601-2-1:1998) EN 60601-2-1:1998/A1:2002 (IEC 60601-2-1:1998/A1:2002) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
206.	EN 60601-2-2:2009 Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories (IEC 60601-2-2:2009) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
207.	EN 60601-2-3:1993 Medical electrical equipment - Part 2: Particular requirements for the safety of short-wave therapy equipment (IEC 60601-2-3:1991) EN 60601-2-3:1993/A1:1998 (IEC 60601-2-3:1991/A1:1998) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
208.	EN 60601-2-4:2003 Medical electrical equipment - Part 2-4: Particular requirements for the safety of cardiac defibrillators (IEC 60601-2-4:2002) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
209.	EN 60601-2-5:2000 Medical electrical equipment - Part 2-5: Particular requirements for the safety of ultrasonic physiotherapy equipment (IEC 60601-2-5:2000) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
210.	EN 60601-2-8:1997 Medical electrical equipment - Part 2: Particular requirements for the safety of therapeutic X-ray equipment operating in the range 10 kV to 1 MV (IEC 60601-2-8:1987) EN 60601-2-8:1997/A1:1997 (IEC 60601-2-8:1987/A1:1997) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
211.	EN 60601-2-10:2000 Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators (IEC 60601-2-10:1987) EN 60601-2-10:2000/A1:2001 (IEC 60601-2-10:1987/A1:2001) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
212.	EN 60601-2-11:1997 Medical electrical equipment - Part 2-11: Particular requirements for the safety of gamma beam therapy equipment (IEC 60601-2-11:1997) EN 60601-2-11:1997/A1:2004 (IEC 60601-2-11:1997/A1:2004) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
213.	EN 60601-2-12:2006 Medical electrical equipment - Part 2-12: Particular requirements for the safety of lung ventilators - Critical care ventilators (IEC 60601-2-12:2001) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
214.	EN 60601-2-13:2006 Medical electrical equipment - Part 2-13: Particular requirements for the safety and essential performance of anaesthetic systems (IEC 60601-2-13:2003) EN 60601-2-13:2006/A1:2007 (IEC 60601-2-13:2003/A1:2006) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
215.	EN 60601-2-16:1998 Medical electrical equipment - Part 2-16: Particular requirements for the safety of haemodialysis, haemodiafiltration and haemofiltration equipment (IEC 60601-2-16:1998) EN 60601-2-16:1998/AC:1999 Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

No	Reference of the standard
216.	EN 60601-2-17:2004 Medical electrical equipment - Part 2-17: Particular requirements for the safety of automatically-controlled brachytherapy afterloading equipment (IEC 60601-2-17:2004) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
217.	EN 60601-2-18:1996 Medical electrical equipment - Part 2-18: Particular requirements for the safety of endoscopic equipment (IEC 60601-2-18:1996) EN 60601-2-18:1996/A1:2000 (IEC 60601-2-18:1996/A1:2000) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
218.	EN 60601-2-19:2009 Medical electrical equipment - Part 2-19: Particular requirements for the basic safety and essential performance of infant incubators (IEC 60601-2-19:2009) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
219.	EN 60601-2-20:2009 Medical electrical equipment - Part 2-20: Particular requirements for the basic safety and essential performance of infant transport incubators (IEC 60601-2-20:2009) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
220.	EN 60601-2-21:2009 Medical electrical equipment - Part 2-21: Particular requirements for the basic safety and essential performance of infant radiant warmers (IEC 60601-2-21:2009) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
221.	EN 60601-2-22:1996 Medical electrical equipment - Part 2: Particular requirements for the safety of diagnostic and therapeutic laser equipment (IEC 60601-2-22:1995) Notice: This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
222.	EN 60601-2-23:2000 Medical electrical equipment - Part 2-23: Particular requirements for the safety, including essential performance, of transcutaneous partial pressure monitoring equipment (IEC 60601-2-23:1999) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
223.	EN 60601-2-24:1998 Medical electrical equipment - Part 2-24: Particular requirements for the safety of infusion pumps and controllers (IEC 60601-2-24:1998) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
224.	EN 60601-2-25:1995 Medical electrical equipment - Part 2-25: Particular requirements for the safety of electrocardiographs (IEC 60601-2-25:1993) EN 60601-2-25:1995/A1:1999 (IEC 60601-2-25:1993/A1:1999) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
225.	EN 60601-2-26:2003 Medical electrical equipment - Part 2-26: Particular requirements for the safety of electroencephalographs (IEC 60601-2-26:2002) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
226.	EN 60601-2-27:2006 Medical electrical equipment - Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment (IEC 60601-2-27:2005) EN 60601-2-27:2006/AC:2006 Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

No	Reference of the standard
227.	EN 60601-2-28:2010 Medical electrical equipment - Part 2-28: Particular requirements for the basic safety and essential performance of X-ray tube assemblies for medical diagnosis (IEC 60601-2-28:2010) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
228.	EN 60601-2-29:2008 Medical electrical equipment - Part 2-29: Particular requirements for the basic safety and essential performance of radiotherapy simulators (IEC 60601-2-29:2008) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
229.	EN 60601-2-30:2000 Medical electrical equipment - Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non- invasive blood pressure monitoring equipment (IEC 60601-2-30:1999) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
230.	EN 60601-2-33:2010 Medical electrical equipment - Part 2-33: Particular requirements for the basic safety and essential performance of magnetic resonance equipment for medical diagnosis (IEC 60601-2-33:2010) EN 60601-2-33:2010/A1:2015 (IEC 60601-2-33:2010/A1:2013) EN 60601-2-33:2010/A2:2015 (IEC 60601-2-33:2010/A2:2015) EN 60601-2-33:2010/AC:2016-03 EN 60601-2-33:2010/A12:2016
231.	EN 60601-2-34:2000 Medical electrical equipment - Part 2-34: Particular requirements for the safety, including essential performance, of invasive blood pressure monitoring equipment (IEC 60601-2-34:2000) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
232.	EN 60601-2-36:1997 Medical electrical equipment - Part 2: Particular requirements for the safety of equipment for extracorporeally induced lithotripsy (IEC 60601-2-36:1997) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
233.	EN 60601-2-37:2008 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment (IEC 60601-2-37:2007) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
234.	EN 60601-2-39:2008 Medical electrical equipment - Part 2-39: Particular requirements for basic safety and essential performance of peritoneal dialysis equipment (IEC 60601-2-39:2007) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
235.	EN 60601-2-40:1998 Medical electrical equipment - Part 2-40: Particular requirements for the safety of electromyographs and evoked response equipment (IEC 60601-2-40:1998) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
236.	EN 60601-2-41:2009 Medical electrical equipment - Part 2-41: Particular requirements for basic safety and essential performance of surgical luminaires and luminaires for diagnosis (IEC 60601-2-41:2009) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
237.	EN 60601-2-43:2010 Medical electrical equipment - Part 2-43: Particular requirements for basic safety and essential performance of X-ray equipment for interventional procedures (IEC 60601-2-43:2010) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

No	Reference of the standard
238.	EN 60601-2-44:2009 Medical electrical equipment - Part 2-44: Particular requirements for the basic safety and essential performance of X-ray equipment for computed tomography (IEC 60601-2-44:2009) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
239.	EN 60601-2-45:2001 Medical electrical equipment - Part 2-45: Particular requirements for the safety of mammographic X-ray equipment and mammographic stereotactic devices (IEC 60601-2-45:2001) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
240.	EN 60601-2-46:1998 Medical electrical equipment - Part 2-46: Particular requirements for the safety of operating tables (IEC 60601-2-46:1998) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
241.	EN 60601-2-47:2001 Medical electrical equipment - Part 2-47: Particular requirements for the safety, including essential performance, of ambulatory electrocardiographic systems (IEC 60601-2-47:2001) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
242.	EN 60601-2-49:2001 Medical electrical equipment - Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment (IEC 60601-2-49:2001) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
243.	EN 60601-2-50:2009 Medical electrical equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment (IEC 60601-2-50:2009) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
244.	EN 60601-2-51:2003 Medical electrical equipment - Part 2-51: Particular requirements for safety, including essential performance, of recording and analysing single channel and multichannel electrocardiographs (IEC 60601-2-51:2003) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
245.	EN 60601-2-52:2010 Medical electrical equipment - Part 2-52: Particular requirements for basic safety and essential performance of medical beds (IEC 60601-2-52:2009) EN 60601-2-52:2010/AC:2011 Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
246.	EN 60601-2-54:2009 Medical electrical equipment - Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy (IEC 60601-2-54:2009) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
247.	EN 60627:2001 Diagnostic X-ray imaging equipment - Characteristics of general purpose and mammographic anti-scatter grids (IEC 60627:2001) EN 60627:2001/AC:2002 Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
248.	EN 60645-1:2001 Electroacoustics - Audiological equipment - Part 1: Pure-tone audiometers (IEC 60645-1:2001) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

No	Reference of the standard
249.	EN 60645-2:1997 Audiometers - Part 2: Equipment for speech audiometry (IEC 60645-2:1993) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
250.	EN 60645-3:2007 Electroacoustics - Audiometric equipment - Part 3: Test signals of short duration (IEC 60645-3:2007) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
251.	EN 60645-4:1995 Audiometers - Part 4: Equipment for extended high-frequency audiometry (IEC 60645-4:1994) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
252.	EN 61217:2012 Radiotherapy equipment - Coordinates, movements and scales (IEC 61217:2011)
253.	EN 61676:2002 Medical electrical equipment - Dosimetric instruments used for non-invasive measurement of X-ray tube voltage in diagnostic radiology (IEC 61676:2002) EN 61676:2002/A1:2009 (IEC 61676:2002/A1:2008) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
254.	EN 62083:2009 Medical electrical equipment - Requirements for the safety of radiotherapy treatment planning systems (IEC 62083:2009) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
255.	EN 62220-1:2004 Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1: Determination of the detective quantum efficiency (IEC 62220-1:2003) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
256.	EN 62220-1-2:2007 Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-2: Determination of the detective quantum efficiency - Detectors used in mammography (IEC 62220-1-2:2007) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
257.	EN 62220-1-3:2008 Medical electrical equipment - Characteristics of digital X-ray imaging devices - Part 1-3: Determination of the detective quantum efficiency - Detectors used in dynamic imaging (IEC 62220-1-3:2008) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
258.	EN 62304:2006 Medical device software - Software life-cycle processes (IEC 62304:2006) EN 62304:2006/AC:2008 Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
259.	EN 62366:2008 Medical devices - Application of usability engineering to medical devices (IEC 62366:2007) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
260.	EN 80601-2-35:2009 Medical electrical equipment - Part 2-35: Particular requirements for the basic safety and essential performance of heating devices using blankets, pads and mattresses and intended for heating in medical use (IEC 80601-2-35:2009) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
261.	EN 80601-2-58:2009 Medical electrical equipment - Part 2-58: Particular requirements for the basic safety and essential performance of lens removal devices and vitrectomy devices for ophthalmic surgery (IEC 80601-2-58:2008) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

No	Reference of the standard
262.	EN 80601-2-59:2009 Medical electrical equipment - Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening (IEC 80601-2-59:2008) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
263.	EN ISO 81060-1:2012 Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type (ISO 81060-1:2007)
264.	EN ISO 81060-2:2019 Non-invasive sphygmomanometers - Part 2: Clinical investigation of intermittent automated measurement type (ISO 81060-2:2018)

ANNEX II

No	Reference of the standard
1.	EN ISO 10993-11:2009 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2006)
2.	EN ISO 11137-1:2015 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006, including Amd 1:2013)
3.	EN ISO 11990-1:2014 Lasers and laser-related equipment - Determination of laser resistance of tracheal tubes - Part 1: Tracheal tube shaft (ISO 11990-1:2011)
4.	EN ISO 11990-2:2014 Lasers and laser-related equipment - Determination of laser resistance of tracheal tubes - Part 2: Tracheal tube cuffs (ISO 11990-2:2010)
5.	EN ISO 13408-2:2011 Aseptic processing of health care products - Part 2: Filtration (ISO 13408-2:2003)
6.	EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) EN ISO 13485:2016/AC:2016
7.	EN 13976-2:2011 Rescue systems - Transportation of incubators - Part 2: System requirements
8.	EN 14683:2005 Surgical masks - Requirements and test methods
9.	EN ISO 15747:2011 Plastic containers for intravenous injections (ISO 15747:2010)
10.	EN ISO 15883-4:2009 Washer-disinfectors - Part 4: Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes (ISO 15883-4:2008)
11.	EN ISO 17664:2004 Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices (ISO 17664:2004)
12.	EN ISO 21987:2009 Ophthalmic optics - Mounted spectacle lenses (ISO 21987:2009)

COMMISSION IMPLEMENTING DECISION (EU) 2020/438

of 24 March 2020

on the harmonised standards for active implantable medical devices drafted in support of Council Directive 90/385/EEC

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(6) thereof,

Whereas:

(1) In accordance with Article 5(1) of Council Directive 90/385/EEC ([2]) Member States are to presume compliance with the essential requirements referred to in Article 3 of that Directive in respect of active implantable medical devices which are in conformity with the relevant national standards adopted pursuant to the harmonised standards the references of which have been published in the *Official Journal of the European Union*.

(2) By letters BC/CEN/CENELEC/09/89 of 19 December 1991 and M/295 of 9 September 1999, the Commission made requests to the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (Cenelec) for the drafting of new harmonised standards and the revision of existing harmonised standards in support of Directive 90/385/EEC.

(3) On the basis of the request M/295 of 9 September 1999, CEN revised the harmonised standard EN ISO 10993-11:2009, the reference of which has been published in the *Official Journal of the European Union* ([3]), in order to include the latest technical and scientific progress. This resulted in the adoption of the harmonised standard EN ISO 10993-11:2018.

(4) The Commission together with CEN has assessed whether the harmonised standard EN ISO 10993-11:2018 complies with the request.

(5) The harmonised standard EN ISO 10993-11:2018 satisfies the requirements which it aims to cover and which are set out in Directive 90/385/EEC. It is therefore appropriate to publish the reference of that standard in the *Official Journal of the European Union*.

(6) The harmonised standard EN ISO 10993-11:2018 replaces the harmonised standard EN ISO 10993-11:2009. It is therefore necessary to withdraw the reference of standard EN ISO 10993-11:2009 from the *Official Journal of the European Union*. In order to give manufacturers sufficient time to adapt their products to the revised specifications in standard EN ISO 10993-11:2018, it is necessary to defer the withdrawal of the reference of standard EN ISO 10993-11:2009.

(7) On the basis of the request BC/CEN/CENELEC/09/89 of 19 December 1991, CEN revised the harmonised standards EN ISO 11137-1:2015, EN ISO 13408-2:2011 and EN ISO 13485:2016, the references of which have been published in the *Official Journal of the European Union* ([4]), in order to include the latest technical and scientific progress. This resulted in the adoption of the harmonised standards EN ISO 11137-1:2015/A2:2019 and EN ISO 13408-2:2018 and the corrigendum EN ISO 13485:2016/AC:2018.

([1]) OJ L 316, 14.11.2012, p. 12.
([2]) 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).
([3]) OJ C 389, 17.11.2017, p. 22.
([4]) OJ C 389, 17.11.2017, p. 22.

(8) The Commission together with CEN has assessed whether the harmonised standards EN ISO 11137-1:2015/A2:2019 and EN ISO 13408-2:2018 and the corrigendum EN ISO 13485:2016/AC:2018 comply with the request.

(9) The harmonised standards EN ISO 11137-1:2015/A2:2019 and EN ISO 13408-2:2018 and the corrigendum EN ISO 13485:2016/AC:2018 satisfy the requirements which they aim to cover and which are set out in Directive 90/385/EEC. It is therefore appropriate to publish the references of those standards and of the corrigendum in the *Official Journal of the European Union*.

(10) The harmonised standards EN ISO 11137-1:2015/A2:2019, EN ISO 13408-2:2018 and the corrigendum EN ISO 13485:2016/AC:2018 replace the harmonised standards EN ISO 11137-1:2015 and EN ISO 13408-2:2011 and the corrigendum EN ISO 13485:2016/AC:2016 respectively. It is therefore necessary to withdraw the references of the harmonised standard EN ISO 11137-1:2015 and EN ISO 13408-2:2011 and of corrigendum EN ISO 13485:2016/AC:2016 from the *Official Journal of the European Union*. In order to give manufacturers sufficient time to adapt their products to the revised specifications in the harmonised standards EN ISO 11137-1:2015/A2:2019 and EN ISO 13408-2:2018 and the corrigendum EN ISO 13485:2016/AC:2018, it is necessary to defer the withdrawal of the references of harmonised standards EN ISO 11137-1:2015 and EN ISO 13408-2:2011 and of corrigendum EN ISO 13485:2016/AC:2016.

(11) On the basis of the request BC/CEN/CENELEC/09/89 of 19 December 1991, CEN drafted the new harmonised standard EN ISO 25424:2019. The Commission together with CEN has assessed whether that standard complies with the request.

(12) The harmonised standard EN ISO 25424:2019 satisfies the requirements which it aims to cover and which are set out in Directive 90/385/EEC. It is therefore appropriate to publish the reference of that standard in the *Official Journal of the European Union*.

(13) In the interests of clarity and legal certainty, a complete list of references of harmonised standards drafted in support of Directive 90/385/EEC and satisfying the essential requirements they aim to cover should be published in one act. The other references of standards published in the Commission communication 2017/C 389/02 ([5]) should therefore also be included in this Decision. That Communication should therefore be repealed from the date of entry into force of this Decision. However, it should continue to apply in respect of the references of the harmonised standards that are withdrawn by this Decision, given that it is necessary to defer withdrawal of those references.

(14) In accordance with the second subparagraph of Article 120(2) of Regulation (EU) 2017/745 of the European Parliament and of the Council ([6]), certificates issued by notified bodies in accordance with Directive 90/385/EEC from 25 May 2017 are to remain valid until the end of the period indicated on the certificate, which is not to exceed five years from its issuance. They are, however, to become void at the latest on 27 May 2024. In accordance with the first subparagraph of Article 120(3) of Regulation (EU) 2017/745 a device which has a certificate that was issued in accordance with Directive 90/385/EEC and that is valid by virtue of Article 120(2) of Regulation (EU) 2017/745, may be placed on the market or put into service until 26 May 2024, provided that from 26 May 2020 it continues to comply with Directive 90/385/EEC, and provided there are no significant changes in the design and intended purpose. This Decision should therefore apply only until 26 May 2024.

(15) The requirements for implantable medical devices laid down in Directive 90/385/EEC are different from those laid down in Regulation (EU) 2017/745. The standards drafted in support of Directive 90/385/EEC should therefore not be used to demonstrate conformity with the requirements of Regulation (EU) 2017/745.

(16) Compliance with a harmonised standard confers a presumption of conformity with the corresponding essential requirements set out in Union harmonisation legislation from the date of publication of the reference of such standard in the *Official Journal of the European Union*. This Decision should therefore enter into force on the date of its publication,

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([5]) Commission communication in the framework of the implementation of Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices (2017/C 389/02) (OJ C 389, 17.11.2017, p. 22).

([6]) 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).

HAS ADOPTED THIS DECISION:

Article 1

The references of the harmonised standards for active implantable medical devices drafted in support of Directive 90/385/EEC and listed in Annex I to this Decision are hereby published in the *Official Journal of the European Union*.

Article 2

Commission communication 2017/C 389/02 is repealed. It shall continue to apply until 30 September 2021 in respect of the references of the harmonised standards listed in Annex II to this Decision.

Article 3

The harmonised standards for active implantable medical devices drafted in support of Directive 90/385/EEC and listed in Annexes I and II to this Decision may not be used to confer presumption of conformity with the requirements of Regulation (EU) 2017/745.

Article 4

This Decision shall enter into force on the day of its publication in the *Official Journal of the European Union*.

It shall apply until 26 May 2024.

Done at Brussels, 24 March 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

No	Reference of the standard
1.	EN 556-1:2001 Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices EN 556-1:2001/AC:2006
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
3.	EN 1041:2008 Information supplied by the manufacturer of medical devices
4.	EN ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009) EN ISO 10993-1:2009/AC:2010
5.	EN ISO 10993-3:2014 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2014)
6.	EN ISO 10993-4:2009 Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood (ISO 10993-4:2002, including Amd 1:2006)
7.	EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)
8.	EN ISO 10993-6:2009 Biological evaluation of medical devices - Part 6: Tests for local effects after implantation (ISO 10993-6:2007)
9.	EN ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (ISO 10993-7:2008) EN ISO 10993-7:2008/AC:2009
10.	EN ISO 10993-9:2009 Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products (ISO 10993-9:2009)
11.	EN ISO 10993-11:2018 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2017)
12.	EN ISO 10993-12:2012 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2012)
13.	EN ISO 10993-13:2010 Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices (ISO 10993-13:2010)
14.	EN ISO 10993-16:2010 Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables (ISO 10993-16:2010)
15.	EN ISO 10993-17:2009 Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances (ISO 10993-17:2002)

No	Reference of the standard
16.	EN ISO 10993-18:2009 Biological evaluation of medical devices - Part 18: Chemical characterization of materials (ISO 10993-18:2005)
17.	EN ISO 11135-1:2007 Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11135-1:2007)
18.	EN ISO 11137-1:2015 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006, including Amd 1:2013) EN ISO 11137-1:2015/A2:2019
19.	EN ISO 11137-2:2015 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:2013)
20.	EN ISO 11138-2:2009 Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138-2:2006)
21.	EN ISO 11138-3:2009 Sterilization of health care products - Biological indicators - Part 3: Biological indicators for moist heat sterilization processes (ISO 11138-3:2006)
22.	EN ISO 11140-1:2009 Sterilization of health care products - Chemical indicators - Part 1: General requirements (ISO 11140-1:2005)
23.	EN ISO 11607-1:2009 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006)
24.	EN ISO 11737-1:2006 Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2006) EN ISO 11737-1:2006/AC:2009
25.	EN ISO 11737-2:2009 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2009)
26.	EN ISO 13408-1:2015 Aseptic processing of health care products - Part 1: General requirements (ISO 13408-1:2008, including Amd 1:2013)
27.	EN ISO 13408-2:2018 Aseptic processing of health care products - Part 2: Sterilizing filtration (ISO 13408-2:2018)
28.	EN ISO 13408-3:2011 Aseptic processing of health care products - Part 3: Lyophilization (ISO 13408-3:2006)
29.	EN ISO 13408-4:2011 Aseptic processing of health care products - Part 4: Clean-in-place technologies (ISO 13408-4:2005)
30.	EN ISO 13408-5:2011 Aseptic processing of health care products - Part 5: Sterilization in place (ISO 13408-5:2006)

No	Reference of the standard
31.	EN ISO 13408-6:2011 Aseptic processing of health care products - Part 6: Isolator systems (ISO 13408-6:2005)
32.	EN ISO 13408-7:2015 Aseptic processing of health care products - Part 7: Alternative processes for medical devices and combination products (ISO 13408-7:2012)
33.	EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) EN ISO 13485:2016/AC:2018
34.	EN ISO 14155:2011 Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2011) EN ISO 14155:2011/AC:2011
35.	EN ISO 14937:2009 Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices (ISO 14937:2009)
36.	EN ISO 14971:2012 Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
37.	EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements (ISO 15223-1:2016, Corrected version 2017-03)
38.	EN ISO 17665-1:2006 Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665-1:2006)
39.	EN ISO 25424:2019 Sterilization of health care products - Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 25424:2018)
40.	EN 45502-1:1997 Active implantable medical devices - Part 1: General requirements for safety, marking and information to be provided by the manufacturer
41.	EN 45502-2-1:2003 Active implantable medical devices - Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (cardiac pacemakers) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
42.	EN 45502-2-2:2008 Active implantable medical devices - Part 2-2: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (includes implantable defibrillators) EN 45502-2-2:2008/AC:2009 Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
43.	EN 45502-2-3:2010 Active implantable medical devices - Part 2-3: Particular requirements for cochlear and auditory brainstem implant systems Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

No	Reference of the standard
44.	EN 60601-1:2006 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005) EN 60601-1:2006/AC:2010 EN 60601-1:2006/A1:2013 (IEC 60601-1:2005/A1:2012)
45.	EN 60601-1-6:2010 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability (IEC 60601-1-6:2010) Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.
46.	EN 62304:2006 Medical device software - Software life-cycle processes (IEC 62304:2006) EN 62304:2006/AC:2008 Notice: This European standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

ANNEX II

No	Reference of the standard
1.	EN ISO 10993-11:2009 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2006)
2.	EN ISO 11137-1:2015 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006, including Amd 1:2013)
3.	EN ISO 13408-2:2011 Aseptic processing of health care products - Part 2: Filtration (ISO 13408-2:2003)
4.	EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) EN ISO 13485:2016/AC:2016

COMMISSION IMPLEMENTING DECISION (EU) 2020/439

of 24 March 2020

on the harmonised standards for *in vitro* diagnostic medical devices drafted in support of Directive 98/79/EC of the European Parliament and of the Council

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(6) thereof,

Whereas:

(1) In accordance with Article 5(1) of Directive 98/79/EC of the European Parliament and of the Council ([2]), Member States are to presume compliance with the essential requirements referred to in Article 3 of that Directive in respect of in vitro diagnostic medical devices which are in conformity with the relevant national standards transposing the harmonised standards the reference numbers of which have been published in the *Official Journal of the European Union*.

(2) By letter BC/CEN/CENELEC/09/89 of 19 December 1991, the Commission made a request to the European Committee for Standardisation (CEN) and the European Committee for Electrotechnical Standardisation (Cenelec) for the drafting of new harmonised standards and the revision of existing harmonised standards in support of Directive 98/79/EC.

(3) On the basis of the request BC/CEN/CENELEC/09/89 of 19 December 1991, CEN revised the harmonised standards EN ISO 11137-1:2015, EN ISO 13408-2:2011 and EN ISO 13485:2016, the references of which have been published in the *Official Journal of the European Union* ([3]), in order to include the latest technical and scientific progress. This resulted in the adoption of the harmonised standards EN ISO 11137-1:2015/A2:2019 and EN ISO 13408-2:2018 and the corrigendum EN ISO 13485:2016/AC:2018.

(4) The Commission together with CEN has assessed whether the harmonised standards EN ISO 11137-1:2015/A2:2019 and EN ISO 13408-2:2018 and the corrigendum EN ISO 13485:2016/AC:2018 comply with the request.

(5) The harmonised standards EN ISO 11137-1:2015/A2:2019 and EN ISO 13408-2:2018 and the corrigendum EN ISO 13485:2016/AC:2018 satisfy the requirements which they aim to cover and which are set out in Directive 98/79/EC. It is therefore appropriate to publish the references of those standards and of the corrigendum in the *Official Journal of the European Union*.

(6) The harmonised standards EN ISO 11137-1:2015/A2:2019 and EN ISO 13408-2:2018 and the corrigendum EN ISO 13485:2016/AC:2018 replace the harmonised standards EN ISO 11137-1:2015 and EN ISO 13408-2:2011 and the corrigendum EN ISO 13485:2016/AC:2016 respectively. It is therefore necessary to withdraw the references of the harmonised standards EN ISO 11137-1:2015 and EN ISO 13408-2:2011 and the corrigendum EN ISO 13485:2016/AC:2016 from the *Official Journal of the European Union*. In order to give manufacturers sufficient time to adapt their products to the revised specifications in standards EN ISO 11137-1:2015/A2:2019, EN ISO 13408-2:2018 and the corrigendum EN ISO 13485:2016/AC:2018, it is necessary to defer the withdrawal of the reference of the standards EN ISO 11137-1:2015, EN ISO 13408-2:2011 and the corrigendum EN ISO 13485:2016/AC:2016.

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

([2]) 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).

([3]) OJ C 389, 17.11.2017, p. 62.

(7) On the basis of the request BC/CEN/CENELEC/09/89 of 19 December 1991, CEN drafted the new harmonised standard EN ISO 25424:2019. The Commission together with CEN has assessed whether that standard complies with the request.

(8) The harmonised standard EN ISO 25424:2019 satisfies the requirements which it aims to cover and which are set out in Directive 98/79/EC. It is therefore appropriate to publish the reference of that standard in the *Official Journal of the European Union*.

(9) In the interests of clarity and legal certainty, a complete list of references of harmonised standards drafted in support of Directive 98/79/EC and satisfying the essential requirements they aim to cover should be published in one act. The other references of standards published in the Commission communication 2017/C 389/04 ([4]) should therefore also be included in this Decision. That Communication should therefore be repealed from the date of entry into force of this Decision. However, it should continue to apply in respect of the references of the standards that are withdrawn by this Decision, given that it is necessary to defer the withdrawal of those references.

(10) In accordance with the second subparagraph of Article 110(2) of Regulation (EU) 2017/746 of the European Parliament and of the Council ([5]) certificates issued by notified bodies in accordance with Directive 98/79/EC from 25 May 2017 are to become void by 27 May 2024. In accordance with the first subparagraph of Article 110(3) of Regulation (EU) 2017/746 a device with a certificate that was issued in accordance with Directive 98/79/EC and which is valid by virtue of Article 110(2) of Regulation (EU) 2017/746 may only be placed on the market or put into service provided that from 26 May 2022 it continues to comply with Directive 98/79/EC, and provided there are no significant changes in the design and intended purpose. This Decision should therefore apply only until 26 May 2024.

(11) The requirements for *in vitro* diagnostic medical devices laid down in Directive 98/79/EC are different from those laid down in Regulation (EU) 2017/746. The standards drafted in support of Directive 98/79/EC should therefore not be used to demonstrate conformity with the requirements of Regulation (EU) 2017/746.

(12) Compliance with a harmonised standard confers a presumption of conformity with the corresponding essential requirements set out in Union harmonisation legislation from the date of publication of the reference of such standard in the *Official Journal of the European Union*. This Decision should therefore enter into force on the date of its publication,

HAS ADOPTED THIS DECISION:

Article 1

The references of the harmonised standards for *in vitro* diagnostic medical devices drafted in support of Directive 98/79/EC and listed in Annex I to this Decision are hereby published in the *Official Journal of the European Union*.

Article 2

Commission communication 2017/C 389/04 is repealed. It shall continue to apply until 30 September 2021 in respect of the references of the harmonised standards listed in Annex II to this Decision.

Article 3

The harmonised standards for *in vitro* diagnostic medical devices drafted in support of Directive 98/79/EC and listed in Annexes I and II to this Decision may not be used to confer presumption of conformity with the requirements of Regulation (EU) 2017/746.

([4]) Commission communication in the framework of the implementation of the Directive 98/79/EC of the European Parliament and of the Council on *in vitro* diagnostic medical devices (2017/C 389/04) (OJ C 389, 17.11.2017, p. 62).

([5]) 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).

Article 4

This Decision shall enter into force on the day of its publication in the *Official Journal of the European Union*.

It shall apply until 26 May 2024.

Done at Brussels, 24 March 2020.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX I

No	Reference of the standard
1.	EN 556-1:2001 Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices EN 556-1:2001/AC:2006
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
3.	EN ISO 11137-1:2015 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006, including Amd 1:2013) EN ISO 11137-1:2015/A2:2019
4.	EN ISO 11137-2:2015 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:2013)
5.	EN ISO 11737-2:2009 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2009)
6.	EN 12322:1999 In vitro diagnostic medical devices - Culture media for microbiology - Performance criteria for culture media EN 12322:1999/A1:2001
7.	EN ISO 13408-1:2015 Aseptic processing of health care products - Part 1: General requirements (ISO 13408-1:2008, including Amd 1:2013)
8.	EN ISO 13408-2:2018 Aseptic processing of health care products - Part 2: Sterilizing filtration (ISO 13408-2:2018)
9.	EN ISO 13408-3:2011 Aseptic processing of health care products - Part 3: Lyophilization (ISO 13408-3:2006)
10.	EN ISO 13408-4:2011 Aseptic processing of health care products - Part 4: Clean-in-place technologies (ISO 13408-4:2005)
11.	EN ISO 13408-5:2011 Aseptic processing of health care products - Part 5: Sterilization in place (ISO 13408-5:2006)
12.	EN ISO 13408-6:2011 Aseptic processing of health care products - Part 6: Isolator systems (ISO 13408-6:2005)
13.	EN ISO 13408-7:2015 Aseptic processing of health care products - Part 7: Alternative processes for medical devices and combination products (ISO 13408-7:2012)
14.	EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) EN ISO 13485:2016/AC:2018
15.	EN 13532:2002 General requirements for in vitro diagnostic medical devices for self-testing

No	Reference of the standard
16.	EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices EN 13612:2002/AC:2002
17.	EN 13641:2002 Elimination or reduction of risk of infection related to in vitro diagnostic reagents
18.	EN 13975:2003 Sampling procedures used for acceptance testing of in vitro diagnostic medical devices - Statistical aspects
19.	EN 14136:2004 Use of external quality assessment schemes in the assessment of the performance of in vitro diagnostic examination procedures
20.	EN 14254:2004 In vitro diagnostic medical devices - Single-use receptacles for the collection of specimens, other than blood, from humans
21.	EN 14820:2004 Single-use containers for human venous blood specimen collection
22.	EN ISO 14937:2009 Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices (ISO 14937:2009)
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24.	EN ISO 15193:2009 In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for content and presentation of reference measurement procedures (ISO 15193:2009)
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30.	EN ISO 18113-2:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2009)
31.	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 (ISO 18113-3:2009)
32.	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 (ISO 18113-4:2009)

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ANNEX II

No	Reference of the standard
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