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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

(OJ L 90 I, 25.3.2020, p. 33)

Amended by:

Official Journal

	No	page	date
► <u>M1</u> Commission Implementing Decision (EU) 2021/609 of 14 April 2021	L 129	150	15.4.2021

**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***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Commission communication 2017/C 389/04 is repealed.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.

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.

▼B*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 11737-2:2020 Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2019)
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)

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No	Reference of the standard
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
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)
23.	EN ISO 14971:2012 Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)
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)
25.	EN ISO 15194:2009 In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for certified reference materials and the content of supporting documentation (ISO 15194:2009)
26.	EN ISO 15197:2015 In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus (ISO 15197:2013)

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No	Reference of the standard
27.	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)
28.	EN ISO 17511:2003 In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials (ISO 17511:2003)
29.	EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)
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)
33.	EN ISO 18113-5:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 5: In vitro diagnostic instruments for self-testing (ISO 18113-5:2009)
34.	EN ISO 18153:2003 In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values for catalytic concentration of enzymes assigned to calibrators and control materials (ISO 18153:2003)
35.	EN ISO 20776-1:2006 Clinical laboratory testing and in vitro diagnostic test systems - Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices - Part 1: Reference method for testing the in vitro activity of antimicrobial agents against rapidly growing aerobic bacteria involved in infectious diseases (ISO 20776-1:2006)
36.	EN ISO 23640:2015 In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents (ISO 23640:2011)
37.	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)
38.	EN 61010-2-101:2002 Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
39.	EN 61326-2-6:2006 Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment

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No	Reference of the standard
40.	EN 62304:2006 Medical device software - Software life-cycle processes (IEC 62304:2006) EN 62304:2006/AC:2008
41.	EN 62366:2008 Medical devices - Application of usability engineering to medical devices

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42.	EN ISO 11607-1:2020 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019)
43.	EN ISO 11607-2:2020 Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019)

*ANNEX II*

No	Reference of the standard
1.	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)
2.	EN ISO 13408-2:2011 Aseptic processing of health care products - Part 2: Filtration (ISO 13408-2:2003)
3.	EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016) EN ISO 13485:2016/AC:2016