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)
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)
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)

No	Reference of the standard
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
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

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