

COMMISSION IMPLEMENTING DECISION (EU) 2021/1195**of 19 July 2021****on the harmonised standards for *in vitro* diagnostic medical devices drafted in support of Regulation (EU) 2017/746 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 8 of Regulation (EU) 2017/746 of the European Parliament and of the Council ⁽²⁾, devices that are in conformity with the relevant harmonised standards, or the relevant parts of those standards, the references of which have been published in the *Official Journal of the European Union*, are to be presumed to be in conformity with the requirements of that Regulation covered by those standards or parts thereof.
- (2) By Commission Implementing Decision C(2021) 2406 ⁽³⁾, the Commission made a request to the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (Cenelec) for the revision of existing harmonised standards on *in vitro* diagnostic medical devices developed in support of Directive 98/79/EC of the European Parliament and of the Council ⁽⁴⁾ and the drafting of new harmonised standards in support of Regulation (EU) 2017/746.
- (3) On the basis of the request set out in Implementing Decision C(2021) 2406, CEN revised the existing harmonised standards EN ISO 11135:2014, EN ISO 11137-1:2015, EN ISO 11737-2:2009 and EN ISO 25424:2011, in order to include the latest technical and scientific progress, and to adapt them to the relevant requirements of Regulation (EU) 2017/746. This resulted in the adoption of the new harmonised standards EN ISO 11737-2:2020 and EN ISO 25424:2019, and of the amendments EN ISO 11135:2014/A1:2019 to EN ISO 11135:2014 and EN ISO 11137-1:2015/A2:2019 to EN ISO 11137-1:2015.
- (4) The Commission together with CEN has assessed whether the standards revised and drafted by CEN comply with the request set out in Implementing Decision C(2021) 2406.
- (5) The harmonised standards EN ISO 11737-2:2020 and EN ISO 25424:2019 and the amendments EN ISO 11135:2014/A1:2019 to EN ISO 11135:2014 and EN ISO 11137-1:2015/A2:2019 to EN ISO 11137-1:2015 satisfy the requirements which they aim to cover and which are set out in Regulation (EU) 2017/746. It is therefore appropriate to publish the references of those standards in the *Official Journal of the European Union*.

⁽¹⁾ OJ L 316, 14.11.2012, p. 12.

⁽²⁾ 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).

⁽³⁾ Commission Implementing Decision of 14.4.2021 on a standardisation request to the European Committee for Standardization and the European Committee for Electrotechnical Standardization as regards medical devices in support of Regulation (EU) 2017/745 of the European Parliament and of the Council and *in vitro* diagnostic medical devices in support of Regulation (EU) 2017/746 of the European Parliament and of the Council.

⁽⁴⁾ 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).

- (6) 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 harmonised standards for *in vitro* diagnostic medical devices drafted in support of Regulation (EU) 2017/746 and listed in the Annex to this Decision are hereby published in the *Official Journal of the European Union*.

Article 2

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

Done at Brussels, 19 July 2021.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

No	Reference of the standard
1.	EN ISO 11135:2014 Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 11135:2014) EN ISO 11135:2014/A1:2019
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) EN ISO 11137-1:2015/A2:2019
3.	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)
4.	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)