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Title and reference

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

C/2021/5199

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Text

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*.

(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

([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).

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)

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