COMMISSION IMPLEMENTING DECISION (EU) 2022/729

of 11 May 2022

amending Implementing Decision (EU) 2021/1195 as regards harmonised standards for quality management systems and for application of risk management to medical devices

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(1) 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) Regulation (EU) 2017/746 will replace Directive 98/79/EC of the European Parliament and of the Council ([3]) from 26 May 2022.

(3) By Implementing Decision C(2021) 2406 ([4]), 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 and the drafting of new harmonised standards in support of Regulation (EU) 2017/746.

(4) On the basis of the request set out in Implementing Decision C(2021) 2406, CEN and Cenelec revised harmonised standard EN ISO 14971:2019, the reference of which is not published in the *Official Journal of the European Union*, in order to take into account the latest technical and scientific progress and to adapt it to the requirements of Regulation (EU) 2017/746. This resulted in the adoption of the amendment EN ISO 14971:2019/A11:2021 to harmonised standard EN ISO 14971:2019 on application of risk management to medical devices.

(5) The Commission together with CEN and Cenelec has assessed whether the harmonised standard EN ISO 14971:2019, as amended by EN ISO 14971:2019/A11:2021, complies with the request set out in Implementing Decision C(2021) 2406.

(6) Harmonised standard EN ISO 14971:2019, as amended by EN ISO 14971:2019/A11:2021, satisfies the requirements which it aims to cover and which are set out in Regulation (EU) 2017/746. It is therefore appropriate to publish the reference of harmonised standard EN ISO 14971:2019 and of its amendment 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]) 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).

([4]) Commission Implementing Decision C(2021) 2406 of 14 April 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.

(7) The Annex to Commission Implementing Decision (EU) 2021/1195 ([5]) lists the references of harmonised standards drafted in support of Regulation (EU) 2017/746.

(8) In order to ensure that the references of harmonised standards drafted in support of Regulation (EU) 2017/746 are listed in one act, the reference of harmonised standard EN ISO 14971:2019 and of its amendment should be included in Implementing Decision (EU) 2021/1195.

(9) The references of harmonised standard EN ISO 13485:2016 on quality management systems and its amendment EN ISO 13485:2016/A11:2021 are published by Implementing Decision (EU) 2021/1195. However, that publication does not include the reference of the corrigendum to that standard – EN ISO 13485:2016/AC:2018. The corrigendum corrects only formal aspects of the European foreword and of the informative annexes, without affecting the substance of the harmonised standard. Harmonised standard EN ISO 13485:2016 as amended by EN ISO 13485:2016/A11:2021 and corrected by EN ISO 13485:2016/AC:2018 satisfies the requirements which it aims to cover and which are set out in Regulation (EU) 2017/746. In order to ensure that corrections made by EN ISO 13485:2016/AC:2018 apply for the purposes of the presumption of conformity with the relevant requirements of Regulation (EU) 2017/746, it is necessary to include the reference of that corrigendum in Implementing Decision (EU) 2021/1195. For reasons of legal certainty, the reference of corrigendum EN ISO 13485:2016/AC:2018 should be published in the *Official Journal of the European Union* with retroactive effect.

(10) Implementing Decision (EU) 2021/1195 should therefore be amended accordingly.

(11) 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 day of its publication,

HAS ADOPTED THIS DECISION:

Article 1

The Annex to Implementing Decision (EU) 2021/1195 is amended in accordance with the Annex to this Decision.

Article 2

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

Point 1 of the Annex shall apply from 7 January 2022.

Done at Brussels, 11 May 2022.

For the Commission
The President
Ursula VON DER LEYEN

([5]) 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 (OJ L 258, 20.7.2021, p. 50).

ANNEX

The Annex to Implementing Decision (EU) 2021/1195 is amended as follows:

(1) entry No 7 is replaced by the following:

No	Reference of the standard
‘7.	EN ISO 13485:2016 Medical devices – Quality management systems – Requirements for regulatory purposes (ISO 13485:2016) EN ISO 13485:2016/AC:2018 EN ISO 13485:2016/A11:2021’;

(2) the following entry is added:

No	Reference of the standard
‘10.	EN ISO 14971:2019 Medical devices – Application of risk management to medical devices (ISO 14971:2019) EN ISO 14971:2019/A11:2021’.