

**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 <sup>(1)</sup>, 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 <sup>(2)</sup>, 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 <sup>(3)</sup> from 26 May 2022.
- (3) By Implementing Decision C(2021) 2406 <sup>(4)</sup>, 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*.

<sup>(1)</sup> OJ L 316, 14.11.2012, p. 12.

<sup>(2)</sup> 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).

<sup>(3)</sup> 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).

<sup>(4)</sup> 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 <sup>(\*)</sup> 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

---

<sup>(\*)</sup> 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'.