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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)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Commission Implementing Decision (EU) 2022/15 of 6 January 2022	L 4	16	7.1.2022
►**M2**	Commission Implementing Decision (EU) 2022/729 of 11 May 2022	L 135	31	12.5.2022

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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

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*.

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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)
▼M1 5.	EN ISO 11737-1:2018 Sterilization of health care products – Microbiological methods – Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2018) EN ISO 11737-1:2018/A1:2021
6.	EN ISO 13408-6:2021 Aseptic processing of health care products – Part 6: Isolator systems (ISO 13408-6:2021)
▼M2 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
▼M1 8.	EN ISO 15223-1:2021 Medical devices – Symbols to be used with information to be supplied by the manufacturer – Part 1: General requirements (ISO 15223-1:2021)
9.	EN ISO 17511:2021 *In vitro* diagnostic medical devices – Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples (ISO 17511:2020)
▼M2 10.	EN ISO 14971:2019 Medical devices – Application of risk management to medical devices (ISO 14971:2019) EN ISO 14971:2019/A11:2021