

► B **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
► <u>M1</u>	Commission Implementing Decision (EU) 2022/15 of 6 January 2022	L 4	16	7.1.2022
► <u>M2</u>	Commission Implementing Decision (EU) 2022/729 of 11 May 2022	L 135	31	12.5.2022
► <u>M3</u>	Commission Implementing Decision (EU) 2023/1411 of 4 July 2023	L 170	105	5.7.2023
► <u>M4</u>	Commission Implementing Decision (EU) 2024/817 of 6 March 2024	L 817	1	8.3.2024
► <u>M5</u>	Commission Implementing Decision (EU) 2024/2625 of 8 October 2024	L 2625	1	9.10.2024



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*.

▼ B*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)
▼ <u>M3</u>	
4.	EN ISO 25424:2019 Sterilisation of health care products – Low temperature steam and formaldehyde – Requirements for development, validation and routine control of a sterilisation process for medical devices (ISO 25424:2018) EN ISO 25424:2019/A1:2022
▼ <u>M1</u>	
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)
▼ <u>M2</u>	
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
▼ <u>M1</u>	
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 <i>In vitro</i> diagnostic medical devices – Requirements for establishing metrological traceability of values assigned to calibrators, trueness control materials and human samples (ISO 17511:2020)
▼ <u>M2</u>	
10.	EN ISO 14971:2019 Medical devices – Application of risk management to medical devices (ISO 14971:2019) EN ISO 14971:2019/A11:2021

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No	Reference of the standard
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▼ **M4**

11.	EN ISO 11137-2:2015 Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose (ISO 11137-2:2013) EN ISO 11137-2:2015/A1:2023
12.	EN ISO 11607-1:2020 Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2019) EN ISO 11607-1:2020/A1:2023
13.	EN ISO 11607-2:2020 Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes (ISO 11607-2:2019) EN ISO 11607-2:2020/A1:2023

▼ **M5**

14.	EN ISO 13408-1:2024 Aseptic processing of health care products – Part 1: General requirements (ISO 13408-1:2023)
15.	EN ISO 20916:2024 <i>In vitro</i> diagnostic medical devices – Clinical performance studies using specimens from human subjects – Good study practice (ISO 20916:2019)