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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
►**M3**	Commission Implementing Decision (EU) 2023/1411 of 4 July 2023	L 170	105	5.7.2023
►**M4**	Commission Implementing Decision (EU) 2024/817 of 6 March 2024	L 817	1	8.3.2024
►**M5**	Commission Implementing Decision (EU) 2024/2625 of 8 October 2024	L 2625	1	9.10.2024
►**M6**	Commission Implementing Decision (EU) 2025/679 of 8 April 2025	L 679	1	10.4.2025
►**M7**	Commission Implementing Decision (EU) 2026/197 of 28 January 2026	L 197	1	30.1.2026
►**M8**	Commission Implementing Decision (EU) 2026/1313 of 15 June 2026	L 1313	1	17.6.2026

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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)
▼M3 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
▼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)
▼M8 8a.	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) EN ISO 15223-1:2021/A1:2025
▼M1 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

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No	Reference of the standard
▼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 *In vitro* diagnostic medical devices – Clinical performance studies using specimens from human subjects – Good study practice (ISO 20916:2019)
▼M6	
16.	EN 556-1:2024 Sterilization of medical devices - Requirements for medical devices to be designated ‘STERILE’ - Part 1: Requirements for terminally sterilized medical devices
17.	EN 556-2:2024 Sterilization of medical devices - Requirements for medical devices to be designated ‘STERILE’ - Part 2: Requirements for aseptically processed medical devices
▼M7	
18.	EN ISO 17665:2024 Sterilization of health care products - Moist heat - Requirements for the development, validation and routine control of a sterilization process for medical devices (ISO 17665:2024)
19.	EN ISO 18113-1:2024 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions, and general requirements (ISO 18113-1:2022)
20.	EN ISO 18113-2:2024 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2022)
21.	EN ISO 18113-3:2024 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instruments for professional use (ISO 18113-3:2022)
22.	EN ISO 18113-4:2024 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 4: In vitro diagnostic reagents for self-testing (ISO 18113-4:2022)
23.	EN ISO 18113-5:2024 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 5: In vitro diagnostic instruments for self-testing (ISO 18113-5:2022)