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Legislation	ESO	Reference and title Provision	Start of legal effect	Publication OJ reference	Publication Decision reference	Publication OJ date	End of legal effect	Withdrawal OJ reference	Withdrawal Decision reference	Withdrawal OJ date
2017/746 - In Vitro Diagnostic Medical Devices	CEN	EN 556-1:2024 Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices	10.04.2025	OJ L	2025/679	10.04.2025				
2017/746 - In Vitro Diagnostic Medical Devices	CEN	EN 556-2:2024 Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 2: Requirements for aseptically processed medical devices	10.04.2025	OJ L	2025/679	10.04.2025				
2017/746 - In Vitro Diagnostic Medical Devices	CEN	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	20.07.2021	OJ L 258	2021/1195	20.07.2021				
2017/746 - In Vitro Diagnostic Medical Devices	CEN	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	20.07.2021	OJ L 258	2021/1195	20.07.2021				
2017/746 - In Vitro Diagnostic Medical Devices	CEN	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	08.03.2024	OJ L	2024/817	08.03.2024				
2017/746 - In Vitro Diagnostic Medical Devices	CEN	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	08.03.2024	OJ L	2024/817	08.03.2024				

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2017/746 - In Vitro Diagnostic Medical Devices	CEN	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	08.03.2024	OJ L	2024/817	08.03.2024				
2017/746 - In Vitro Diagnostic Medical Devices	CEN	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	07.01.2022	OJ L 4	2022/15	07.01.2022				
2017/746 - In Vitro Diagnostic Medical Devices	CEN	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)	20.07.2021	OJ L 258	2021/1195	20.07.2021				
2017/746 - In Vitro Diagnostic Medical Devices	CEN	EN ISO 13408-1:2024 Aseptic processing of health care products - Part 1: General requirements (ISO 13408-1:2023)	09.10.2024	OJ L	2024/2625	09.10.2024				
2017/746 - In Vitro Diagnostic Medical Devices	CEN	EN ISO 13408-6:2021 Aseptic processing of health care products - Part 6: Isolator systems (ISO 13408-6:2021)	07.01.2022	OJ L 4	2022/15	07.01.2022				
2017/746 - In Vitro Diagnostic Medical Devices	CEN	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	07.01.2022	OJ L 4	2022/15	07.01.2022				
2017/746 - In Vitro Diagnostic Medical Devices	CEN	EN ISO 14971:2019 Medical devices - Application of risk management to medical devices (ISO 14971:2019) EN ISO 14971:2019/A11:2021	12.05.2022	OJ L 135	2022/729	12.05.2022				

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2017/746 - In Vitro Diagnostic Medical Devices	CEN	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)	07.01.2022	OJ L 4	2022/15	07.01.2022	17.06.2031	OJ L	2026/1313	17.06.2026
2017/746 - In Vitro Diagnostic Medical Devices	CEN	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	17.06.2026	OJ L	2026/1313	17.06.2026				
2017/746 - In Vitro Diagnostic Medical Devices	CEN	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)	07.01.2022	OJ L 4	2022/15	07.01.2022				
2017/746 - In Vitro Diagnostic Medical Devices	CEN	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)	30.01.2026	OJ L	2026/197	30.01.2026				
2017/746 - In Vitro Diagnostic Medical Devices	CEN	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)	30.01.2026	OJ L	2026/197	30.01.2026				
2017/746 - In Vitro Diagnostic Medical Devices	CEN	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)	30.01.2026	OJ L	2026/197	30.01.2026				

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2017/746 - In Vitro Diagnostic Medical Devices	CEN	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)	30.01.2026	OJ L	2026/197	30.01.2026				
2017/746 - In Vitro Diagnostic Medical Devices	CEN	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)	30.01.2026	OJ L	2026/197	30.01.2026				
2017/746 - In Vitro Diagnostic Medical Devices	CEN	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)	30.01.2026	OJ L	2026/197	30.01.2026				
2017/746 - In Vitro Diagnostic Medical Devices	CEN	EN ISO 20916:2024 In vitro diagnostic medical devices - Clinical performance studies using specimens from human subjects - Good study practice (ISO 20916:2019)	09.10.2024	OJ L	2024/2625	09.10.2024				
2017/746 - In Vitro Diagnostic Medical Devices	CEN	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)	20.07.2021	OJ L 258	2021/1195	20.07.2021	05.07.2023	OJ L 170	2023/1411	05.07.2023
2017/746 - In Vitro Diagnostic Medical Devices	CEN	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) EN ISO 25424:2019/A1:2022	05.07.2023	OJ L 170	2023/1411	05.07.2023				

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