THE DEPARTMENT OF HEALTH AND SOCIAL CARE
NOTICE OF PROPOSAL TO PUBLISH
0129/26
of 19 December 2025

references to standards for medical devices in support of the Medical Devices Regulations 2002 (S.I. 2002/618)

1. This notice sets out proposals that:

(a) The references to standards listed in Annex I to this notice be published for the purposes of regulation 3A of S.I. 2002/618 in accordance with paragraph 2 below, and that the list of published standards set out in set out in Annex I to notice 0034/21 be amended in accordance with Annex I to this notice.

(b) The list of references to standards to be removed from publication, set out in Annex II to notice 0034/21, is amended in accordance with Annex II to this notice.

2. The references to standards are proposed to be published and accordingly designated under regulation 3A of S.I. 2002/618 at 00.01 on the 29th day beginning with the date of this notice, unless this notice is withdrawn or amended before that date. Any objection to the proposed publication for this purpose may be made to designatedstandards@businessandtrade.gov.uk

ANNEX I

The list of published standards as set out in Annex I to notice 0034/21 is proposed to be amended as follows:

(1) rows 1, 2, 3, 4, 6, 7, 25, 72, 78, 81, 83, 84, 85, 88, 94, 95, 97, 98 115, 117, 123, 126, 159, 163, 178, 196, 200, 208 and 271 are replaced by the following:

1.	EN 285:2015+A1:2021 Sterilization - Steam sterilizers - Large sterilizers
2.	EN 455-1:2020+A2:2024 Medical gloves for single use - Part 1: Requirements and testing for freedom from holes
3.	EN 455-2:2024 Medical gloves for single use - Part 2: Requirements and testing for physical properties
4.	EN 455-3:2023 Medical gloves for single use - Part 3: Requirements and testing for biological evaluation
6.	EN 556-1:2024 Sterilization of medical devices - Requirements for medical devices to be designated “STERILE” - Part 1: Requirements for terminally sterilized medical devices
7.	EN 556-2:2024 Sterilization of medical devices - Requirements for medical devices to be designated “STERILE” - Part 2: Requirements for aseptically processed medical devices
25.	EN 1865-2:2024 Patient handling equipment used in road ambulances - Part 2: Power assisted stretcher
72.	EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity EN ISO 10993-5:2009+A11:2025
78.	EN ISO 10993-12:2021 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials EN ISO 10993-12:2021+A1:2025
81.	EN ISO 10993-15:2023 Biological evaluation of medical devices – Part 15: Identification and quantification of degradation products from metals and alloys
83.	EN ISO 10993-17:2023 Biological evaluation of medical devices – Part 17: Toxicological risk assessment of medical device constituents

84.	EN ISO 10993-18:2020 Biological evaluation of medical devices – Part 18: Chemical characterization of medical device materials within a risk management process EN ISO 10993-18:2020/A1:2023
85.	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 EN ISO 11135:2014/A1:2019
88.	EN ISO 11137-2:2015 Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose EN ISO 11137-2:2015/A1:2023
94.	EN ISO 11607-1:2020 Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier systems and packaging systems EN ISO 11607-1:2020/A1:2023
95.	EN ISO 11607-2:2020 Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes EN ISO 11607-2:2020/A1:2023
97.	EN ISO 11737-1:2018 Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products EN ISO 11737-1:2018/A1:2021
98.	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
115.	EN ISO 12870:2025 Ophthalmic optics - Spectacle frames - Requirements and test methods
117.	EN ISO 13408-1:2024 Aseptic processing of health care products - Part 1: General requirements
123.	EN ISO 13408-6:2021 Aseptic processing of health care products – Part 6: Isolator systems
126.	EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes EN ISO 13485:2016/AC:2018 EN ISO 13485:2016+A11:2021

159.	EN ISO 14971:2019 Medical devices – Application of risk management to medical devices EN ISO 14971:2019/A11:2021
163.	EN ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
178.	EN ISO 17664-1:2021 Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices
196.	EN ISO 22675:2025 Prosthetics - Testing of ankle-foot devices and foot units - Requirements and test methods
200.	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 EN ISO 25424:2019/A1:2022
208.	EN 60601-1:2006 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance EN 60601-1:2006/AC:2010 EN 60601-1:2006/A1:2013 EN 60601-1:2006/A13:2024
271.	EN 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices EN 62366-1:2015/A1:2020 Informative Note: This standard does not necessarily cover the requirements introduced into the Medical Devices Regulations 2002 by S.I. 2008/2936 (which implemented Directive 2007/747/EC). Manufacturers are advised to check whether all relevant essential requirements are appropriately covered.

(2) the following rows are inserted in sequential order:

28a.	EN 1865-6:2024 Patient handling equipment used in ambulances – Part 6: Powered chairs
76a.	EN ISO 10993-10:2023 Biological evaluation of medical devices – Part 10: Tests for skin sensitisation

84a.	EN ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation EN ISO 10993-23:2021/A1:2025
144a.	EN ISO 14160:2021 Sterilization of health care products - Liquid chemical sterilizing agents for single-use medical devices utilizing animal tissues and their derivatives - Requirements for characterization, development, validation and routine control of a sterilization process for medical devices
178a.	EN ISO 17664-2:2023 Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices – Part 2: Non-critical medical devices

(3) rows 76, 86, 103, 104, 118, 125, 140, 154, 164, 170, 177 and 190 are deleted.

ANNEX II

The list of standards for removal from publication, as set out in Annex II to notice 0034/21, is proposed to be amended as follows:

(1) rows 1 to 12 inclusive are removed.