THE DEPARTMENT OF HEALTH AND SOCIAL CARE
NOTICE OF PROPOSAL TO PUBLISH
0127/25
of 19 December 2025

references to standards for active implantable 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 0032/21 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 0032/21, 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regulation 3A of S.I. 2002/618 at 00.01 on the 29th day beginning with the date of this notice, unless this notice is withdrawn or amended before that date.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 0032/21 is proposed to be amended as follows:

(1) rows 1, 2, 7, 13, 16, 17, 18, 20, 21, 25, 26, 27, 28, 34, 37, 40, 41, 43 and 48 are replaced by the following:

1.	EN 556-1:2024 Sterilization of medical devices - Requirements for medical devices to be designated “STERILE” - Part 1: Requirements for terminally sterilized medical devices
2.	EN 556-2:2024 Sterilization of medical devices - Requirements for medical devices to be designated “STERILE” - Part 2: Requirements for aseptically processed medical devices
7.	EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity EN ISO 10993-5:2009/A11:2025
13.	EN ISO 10993-12:2021 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials EN ISO 10993-12:2021+A1:2025
16.	EN ISO 10993-17:2023 Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances
17.	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
18.	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
21.	EN ISO 11137-2:2015 Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose EN ISO 11137-2:2015/A1:2023
25.	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

26.	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
27.	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
28.	EN ISO 13408-1:2024 Aseptic processing of health care products - Part 1: General requirements
34.	EN ISO 13408-6:2021 Aseptic processing of health care products - Part 6: Isolator systems
37.	EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes EN ISO 13485:2016/A11:2021
40.	EN ISO 14971:2019 Medical devices – Application of risk management to medical devices EN ISO 14971:2019/A11:2021
41.	EN ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
43.	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 EN ISO 25424:2019/A1:2022
48.	EN 60601-1:2006 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance EN 60601-1:2006/A13:2024

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

10a.	EN ISO 10993-10:2023 Biological evaluation of medical devices – Part 10: Tests for skin sensitisation

17a.	EN ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation EN ISO 10993-23:2021/A1:2025
41a.	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
41b.	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) remove rows 11, 19, 29 and 36.

ANNEX II

The list of standards for removal from publication, as set out in Annex II to notice 0032/21, is proposed to be amended as follows:

(1) rows 1 to 4 inclusive are removed.