

THE DEPARTMENT OF HEALTH AND SOCIAL CARE
NOTICE OF PUBLICATION
0127/26
of 17 January 2026

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

This notice confirms that:

- a) The references to standards listed in Annex I to this notice are published for the purposes of regulation 3A of S.I. 2002/618 and accordingly are designated pursuant to that regulation in relation to England and Wales and Scotland. The list of published standards set out in Annex I to notice 0032/21 is amended in accordance with Annex I to this notice from the date of this notice. For clarity, Part 2 of Annex I to this notice sets out the complete list of references to standards which have been published and accordingly are designated for the purposes of S.I. 2002/618 as at the date of 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 from the date of this notice.

ANNEX I

Part 1

The list of published standards as set out in Annex I to notice 0032/21 is to be amended as follows:

- (1) rows 1, 2, 7, 13, 16, 17, 18, 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
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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 I

Part 2

No	Reference of standard
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
3.	EN 1041:2008 Information supplied by the manufacturer of medical devices
4.	EN ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process EN ISO 10993-1:2009/AC:2010
5.	EN ISO 10993-3:2014 Biological evaluation of medical devices - Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
6.	EN ISO 10993-4:2009 Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood
7.	EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009) EN ISO 10993-5:2009/A11:2025
8.	EN ISO 10993-6:2009 Biological evaluation of medical devices - Part 6: Tests for local effects after implantation
9.	EN ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals EN ISO 10993-7:2008/AC:2009
10.	EN ISO 10993-9:2009 Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products
10a.	EN ISO 10993-10:2023 Biological evaluation of medical devices – Part 10: Tests for skin sensitisation

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12.	EN ISO 10993-11:2018 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
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
14.	EN ISO 10993-13:2010 Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices
15.	EN ISO 10993-16:2010 Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables
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
17a.	EN ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation EN ISO 10993-23:2021/A1:2025
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
19.	
20.	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 EN ISO 11137-1:2015/A2:2019
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

22.	EN ISO 11138-2:2009 Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes
23.	EN ISO 11138-3:2009 Sterilization of health care products - Biological indicators - Part 3: Biological indicators for moist heat sterilization processes
24.	EN ISO 11140-1:2009 Sterilization of health care products - Chemical indicators - Part 1: General requirements
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
29.	
30.	EN ISO 13408-2:2018 Aseptic processing of health care products - Part 2: Sterilizing filtration
31.	EN ISO 13408-3:2011 Aseptic processing of health care products - Part 3: Lyophilization
32.	EN ISO 13408-4:2011 Aseptic processing of health care products - Part 4: Clean-in-place technologies
33.	EN ISO 13408-5:2011 Aseptic processing of health care products - Part 5: Sterilization in place
34.	EN ISO 13408-6:2021 Aseptic processing of health care products - Part 6: Isolator systems

35.	EN ISO 13408-7:2015 Aseptic processing of health care products - Part 7: Alternative processes for medical devices and combination products
36.	
37.	EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes EN ISO 13485:2016/A11:2021
38.	EN ISO 14155:2011 Clinical investigation of medical devices for human subjects - Good clinical practice EN ISO 14155:2011/AC:2011
39.	EN ISO 14937:2009 Sterilization of health care products - General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices
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
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
42.	EN ISO 17665-1:2006 Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
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

44.	EN 45502-1:1997 Active implantable medical devices - Part 1: General requirements for safety, marking and information to be provided by the manufacturer
45.	EN 45502-2-1:2003 Active implantable medical devices - Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (cardiac pacemakers) 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.
46.	EN 45502-2-2:2008 Active implantable medical devices - Part 2-2: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (includes implantable defibrillators) EN 45502-2-2:2008/AC:2009 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.
47.	EN 45502-2-3:2010 Active implantable medical devices - Part 2-3: Particular requirements for cochlear and auditory brainstem implant systems 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.
48.	EN 60601-1:2006 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance EN 60601-1:2006/A13:2024
49.	EN 60601-1-6:2010 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability 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.

50.	EN 62304:2006 Medical device software - Software life-cycle processes EN 62304:2006/AC:2008 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.
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ANNEX II

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

- (1) rows 1 to 4 inclusive are removed.