

THE DEPARTMENT OF HEALTH AND SOCIAL CARE
NOTICE OF PUBLICATION
0128/26
of 17 January 2026

**of references to standards for in vitro diagnostic 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 0033/21 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 0033/21, 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 0033/21 is to be amended as follows:

(1) rows 1, 2, 5, 6, 8, 14, 17, 26, 30, 31, 40 and 44 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
5.	EN ISO 11137-2:2015 Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose EN ISO 11137-2:2015/A1:2023
6.	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
8.	EN ISO 13408-1:2024 Aseptic processing of health care products - Part 1: General requirements
14.	EN ISO 13408-6:2021 Aseptic processing of health care products - Part 6: Isolator systems
17.	EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes EN ISO 13485:2016/A11:2021
26.	EN ISO 14971:2019 Medical devices – Application of risk management to medical devices EN ISO 14971:2019/A11:2021
30.	EN ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
31.	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

40.	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 62366-1:2015 Medical devices - Application of usability engineering to medical devices EN 62366-1:2015/A1:2020

(2) the following row is added:

45.	EN ISO 20916:2024 In vitro diagnostic medical devices – Clinical performance studies using specimens from human subjects – Good study practice
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(3) rows 3, 9 and 16 are deleted.

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.	
4.	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
5.	EN ISO 11137-2:2015 Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose EN ISO 11137-2:2015/A1:2023
6.	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
7.	EN 12322:1999 In vitro diagnostic medical devices - Culture media for microbiology - Performance criteria for culture media EN 12322:1999/A1:2001
8.	EN ISO 13408-1:2024 Aseptic processing of health care products - Part 1: General requirements
9.	
10.	EN ISO 13408-2:2018 Aseptic processing of health care products - Part 2: Sterilizing filtration (ISO 13408-2:2018)
11.	EN ISO 13408-3:2011 Aseptic processing of health care products - Part 3: Lyophilization (ISO 13408-3:2006)

12.	EN ISO 13408-4:2011 Aseptic processing of health care products - Part 4: Clean-in-place technologies (ISO 13408-4:2005)
13.	EN ISO 13408-5:2011 Aseptic processing of health care products - Part 5: Sterilization in place (ISO 13408-5:2006)
14.	EN ISO 13408-6:2021 Aseptic processing of health care products - Part 6: Isolator systems
15.	EN ISO 13408-7:2015 Aseptic processing of health care products - Part 7: Alternative processes for medical devices and combination products (ISO 13408-7:2012)
16.	
17.	EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes EN ISO 13485:2016/A11:2021
18.	EN 13532:2002 General requirements for in vitro diagnostic medical devices for self-testing
19.	EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices EN 13612:2002/AC:2002
20.	EN 13641:2002 Elimination or reduction of risk of infection related to in vitro diagnostic reagents
21.	EN 13975:2003 Sampling procedures used for acceptance testing of in vitro diagnostic medical devices - Statistical aspects
22.	EN 14136:2004 Use of external quality assessment schemes in the assessment of the performance of in vitro diagnostic examination procedures
23.	EN 14254:2004 In vitro diagnostic medical devices - Single-use receptacles for the collection of specimens, other than blood, from humans
24.	EN 14820:2004 Single-use containers for human venous blood specimen collection

25.	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
26.	EN ISO 14971:2019 Medical devices – Application of risk management to medical devices EN ISO 14971:2019/A11:2021
27.	EN ISO 15193:2009 In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for content and presentation of reference measurement procedures
28.	EN ISO 15194:2009 In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for certified reference materials and the content of supporting documentation
29.	EN ISO 15197:2015 In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus
30.	EN ISO 15223-1:2021 Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements
31.	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
32.	EN ISO 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements
33.	EN ISO 18113-2:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use
34.	EN ISO 18113-3:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instruments for professional use
35.	EN ISO 18113-4:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 4: In vitro diagnostic reagents for self-testing
36.	EN ISO 18113-5:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 5: In vitro diagnostic instruments for self-testing

37.	<p>EN ISO 18153:2003</p> <p>In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values for catalytic concentration of enzymes assigned to calibrators and control materials</p>
38.	<p>EN ISO 20776-1:2006</p> <p>Clinical laboratory testing and in vitro diagnostic test systems - Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices - Part 1: Reference method for testing the in vitro activity of antimicrobial agents against rapidly growing aerobic bacteria involved in infectious diseases</p>
39.	<p>EN ISO 23640:2015</p> <p>In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents</p>
40.	<p>EN ISO 25424:2019</p> <p>Sterilisation of health care products – Low temperature steam and formaldehyde – Requirements for development, validation and routine control of a sterilisation process for medical devices</p> <p>EN ISO 25424:2019/A1:2022</p>
41.	<p>EN 61010-2-101:2002</p> <p>Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment</p>
42.	<p>EN 61326-2-6:2006</p> <p>Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment</p>
43.	<p>EN 62304:2006</p> <p>Medical device software - Software life-cycle processes</p> <p>EN 62304:2006/AC:2008</p>
44.	<p>EN 62366-1:2015</p> <p>Medical devices - Application of usability engineering to medical devices</p> <p>EN 62366-1:2015/A1:2020</p>
45.	<p>EN ISO 20916:2024</p> <p>In vitro diagnostic medical devices – Clinical performance studies using specimens from human subjects – Good study practice</p>

ANNEX II

The list of standards for removal from publication, as set out in Annex II to notice 0033/21, is amended as follows:

- (1) rows 1 to 3 inclusive are removed.