**THE DEPARTMENT OF HEALTH AND SOCIAL CARE**
**NOTICE OF PUBLICATION**
**0033/21**
**of 1 January 2021**

**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.

b) The references to standards listed in Annex II to this notice are published for the purposes of regulation 3A of S.I. 2002/618 but will be removed from publication from the dates set out in that Annex. Accordingly, each of these standards will not be designated, or give rise to any presumption of conformity, on or after the date set out in respect of it.

ANNEX I

| No | Reference of standard |
|---|---|
| 1. | EN 556-1:2001<br>Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices<br>EN 556-1:2001/AC:2006 |
| 2. | EN 556-2:2015<br>Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 2: Requirements for aseptically processed medical devices |
| 3. | EN ISO 11137-1:2015<br>Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices |
| 4. | EN ISO 11137-1:2015<br>Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices<br>EN ISO 11137-1:2015/A2:2019 |
| 5. | EN ISO 11137-2:2015<br>Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose |
| 6. | EN ISO 11737-2:2009<br>Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process |
| 7. | EN 12322:1999<br>In vitro diagnostic medical devices - Culture media for microbiology - Performance criteria for culture media<br>EN 12322:1999/A1:2001 |
| 8. | EN ISO 13408-1:2015<br>Aseptic processing of health care products - Part 1: General requirements |
| 9. | EN ISO 13408-2:2011<br>Aseptic processing of health care products - Part 2: Filtration |
| 10. | EN ISO 13408-2:2018<br>Aseptic processing of health care products - Part 2: Sterilizing filtration |
| 11. | EN ISO 13408-3:2011<br>Aseptic processing of health care products - Part 3: Lyophilization |
| 12. | EN ISO 13408-4:2011<br>Aseptic processing of health care products - Part 4: Clean-in-place technologies |
| 13. | EN ISO 13408-5:2011<br>Aseptic processing of health care products - Part 5: Sterilization in place |
| 14. | EN ISO 13408-6:2011<br>Aseptic processing of health care products - Part 6: Isolator systems |
| 15. | EN ISO 13408-7:2015<br>Aseptic processing of health care products - Part 7: Alternative processes for medical devices and combination products |
| 16. | EN ISO 13485:2016<br>Medical devices - Quality management systems - Requirements for regulatory purposes<br>EN ISO 13485:2016/AC:2016 |
| 17. | EN ISO 13485:2016<br>Medical devices - Quality management systems - Requirements for regulatory purposes<br>EN ISO 13485:2016/AC:2018 |

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| 18. | EN 13532:2002<br>General requirements for in vitro diagnostic medical devices for self-testing |
| 19. | EN 13612:2002<br>Performance evaluation of in vitro diagnostic medical devices<br>EN 13612:2002/AC:2002 |
| 20. | EN 13641:2002<br>Elimination or reduction of risk of infection related to in vitro diagnostic reagents |
| 21. | EN 13975:2003<br>Sampling procedures used for acceptance testing of in vitro diagnostic medical devices - Statistical aspects |
| 22. | EN 14136:2004<br>Use of external quality assessment schemes in the assessment of the performance of in vitro diagnostic examination procedures |
| 23. | EN 14254:2004<br>In vitro diagnostic medical devices - Single-use receptacles for the collection of specimens, other than blood, from humans |
| 24. | EN 14820:2004<br>Single-use containers for human venous blood specimen collection |
| 25. | EN ISO 14937:2009<br>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 14971:2012<br>Medical devices - Application of risk management to medical devices |
| 27. | EN ISO 15193:2009<br>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<br>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<br>In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus |
| 30. | EN ISO 15223-1:2016<br>Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements |
| 31. | EN ISO 17511:2003<br>In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials |
| 32. | EN ISO 18113-1:2011<br>In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements |
| 33. | EN ISO 18113-2:2011<br>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<br>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<br>In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 4: In vitro diagnostic reagents for self-testing |

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| 36. | EN ISO 18113-5:2011<br>In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 5: In vitro diagnostic instruments for self-testing |
| 37. | EN ISO 18153:2003<br>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 |
| 38. | EN ISO 20776-1:2006<br>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 |
| 39. | EN ISO 23640:2015<br>In vitro diagnostic medical devices - Evaluation of stability of in vitro diagnostic reagents |
| 40. | EN ISO 25424:2019<br>Sterilization of health care products - Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices |
| 41. | EN 61010-2-101:2002<br>Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment |
| 42. | EN 61326-2-6:2006<br>Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 2-6: Particular requirements - In vitro diagnostic (IVD) medical equipment |
| 43. | EN 62304:2006<br>Medical device software - Software life-cycle processes<br>EN 62304:2006/AC:2008 |
| 44. | EN 62366:2008<br>Medical devices - Application of usability engineering to medical devices |

ANNEX II

| No | Reference of standard | Date of removal from publication |
|---|---|---|
| 1. | EN ISO 11137-1:2015<br>Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices | 30 September 2021 |
| 2. | EN ISO 13408-2:2011<br>Aseptic processing of health care products - Part 2: Filtration | 30 September 2021 |
| 3. | EN ISO 13485:2016<br>Medical devices - Quality management systems - Requirements for regulatory purposes<br>EN ISO 13485:2016/AC:2016 | 30 September 2021 |