THE DEPARTMENT OF HEALTH AND SOCIAL CARE
NOTICE OF PUBLICATION
0032/21
of 1 January 2021

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.

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 Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices EN 556-1:2001/AC:2006
2.	EN 556-2:2015 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
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
11.	EN ISO 10993-11:2009 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
12.	EN ISO 10993-11:2018 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
13.	EN ISO 10993-12:2012 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials
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 10993-17:2009 Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances
17.	EN ISO 10993-18:2009 Biological evaluation of medical devices - Part 18: Chemical characterization of materials

18.	EN ISO 11135-1:2007 Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
19.	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
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
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 11607-1:2009 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
26.	EN ISO 11737-1:2006 Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products EN ISO 11737-1:2006/AC:2009
27.	EN ISO 11737-2:2009 Sterilization of medical devices - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
28.	EN ISO 13408-1:2015 Aseptic processing of health care products - Part 1: General requirements
29.	EN ISO 13408-2:2011 Aseptic processing of health care products - Part 2: Filtration
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 13408-6:2011 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.	EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes EN ISO 13485:2016/AC:2016

37.	EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes EN ISO 13485:2016/AC:2018
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 14971:2012 Medical devices - Application of risk management to medical devices
41.	EN ISO 15223-1:2016 Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
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 Sterilization of health care products - Low temperature steam and formaldehyde - Requirements for development, validation and routine control of a sterilization process for medical devices
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) *Notice*: 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).
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 *Notice*: 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).
47.	EN 45502-2-3:2010 Active implantable medical devices - Part 2-3: Particular requirements for cochlear and auditory brainstem implant systems *Notice*: 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).
48.	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
49.	EN 60601-1-6:2010 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability *Notice*: 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).

50.	EN 62304:2006 Medical device software - Software life-cycle processes EN 62304:2006/AC:2008 *Notice*: 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).

ANNEX II

No	Reference of standard	Date of removal from publication
1.	EN ISO 10993-11:2009 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity	30 September 2021
2.	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	30 September 2021
3.	EN ISO 13408-2:2011 Aseptic processing of health care products - Part 2: Filtration	30 September 2021
4.	EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes EN ISO 13485:2016/AC:2016	30 September 2021