IV

(Notices)

NOTICES FROM EUROPEAN UNION INSTITUTIONS, BODIES, OFFICES AND AGENCIES

EUROPEAN COMMISSION

Commission communication in the framework of the implementation of the Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices

(Text with EEA relevance)

(Publication of titles and references of harmonised standards under the directive)

(2012/C 123/01)

ESO [1]	Reference and title of the harmonised standard (and reference document)	First publication OJ	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard Note 1
(1)	(2)	(3)	(4)	(5)
CEN	EN 556-1:2001 Sterilization of medical devices - Requirements for medical devices to be designated 'STERILE' - Part 1: Requirements for terminally sterilized medical devices	31.7.2002	EN 556:1994 + A1:1998 Note 2.1	Date expired (30.4.2002)
	EN 556-1:2001/AC:2006	15.11.2006		
CEN	EN 556-2:2003 Sterilization of medical devices - Requirements for medical devices to be designated 'STERILE' - Part 2: Requirements for aseptically processed medical devices	9.8.2007		
CEN	EN 980:2008 Symbols for use in the labelling of medical devices	23.7.2008	EN 980:2003 Note 2.1	Date expired (31.5.2010)
CEN	EN 1041:2008 Information supplied by the manufacturer of medical devices	19.2.2009	EN 1041:1998 Note 2.1	Date expired (31.8.2011)
CEN	EN ISO 10993-1:2009 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process (ISO 10993-1:2009)	2.12.2009	EN ISO 10993-1:2009 Note 2.1	Date expired (21.3.2010)
	EN ISO 10993-1:2009/AC:2010	18.1.2011		
CEN	EN ISO 10993-4:2009 Biological evaluation of medical devices - Part 4: Selection of tests for interactions with blood (ISO 10993-4:2002, including Amd 1:2006)	2.12.2009	EN ISO 10993-4:2002 Note 2.1	Date expired (21.3.2010)
CEN	EN ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)	2.12.2009	EN ISO 10993-5:1999 Note 2.1	Date expired (31.12.2009)

(1)	(2)	(3)	(4)	(5)
CEN	EN ISO 10993-6:2009 Biological evaluation of medical devices - Part 6: Tests for local effects after implantation (ISO 10993-6:2007)	2.12.2009	EN ISO 10993-6:2007 Note 2.1	Date expired (21.3.2010)
CEN	EN ISO 10993-7:2008 Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals (ISO 10993-7:2008)	7.7.2010		
	EN ISO 10993-7:2008/AC:2009	7.7.2010		
CEN	EN ISO 10993-9:2009 Biological evaluation of medical devices - Part 9: Framework for identification and quantification of potential degradation products (ISO 10993-9:2009)	2.12.2009	EN ISO 10993-9:2009 Note 2.1	Date expired (21.3.2010)
CEN	EN ISO 10993-11:2009 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (ISO 10993-11:2006)	2.12.2009	EN ISO 10993-11:2006 Note 2.1	Date expired (21.3.2010)
CEN	EN ISO 10993-12:2009 Biological evaluation of medical devices - Part 12: Sample preparation and reference materials (ISO 10993-12:2007)	2.12.2009	EN ISO 10993-12:2007 Note 2.1	Date expired (21.3.2010)
CEN	EN ISO 10993-13:2010 Biological evaluation of medical devices - Part 13: Identification and quantification of degradation products from polymeric medical devices (ISO 10993-13:2010)	18.1.2011	EN ISO 10993-13:2009 Note 2.1	Date expired (31.12.2010)
CEN	EN ISO 10993-16:2010 Biological evaluation of medical devices - Part 16: Toxicokinetic study design for degradation products and leachables (ISO 10993-16:2010)	7.7.2010	EN ISO 10993-16:2009 Note 2.1	Date expired (31.8.2010)
CEN	EN ISO 10993-17:2009 Biological evaluation of medical devices - Part 17: Establishment of allowable limits for leachable substances (ISO 10993-17:2002)	2.12.2009	EN ISO 10993-17:2002 Note 2.1	Date expired (21.3.2010)
CEN	EN ISO 10993-18:2009 Biological evaluation of medical devices - Part 18: Chemical characterization of materials (ISO 10993-18:2005)	2.12.2009	EN ISO 10993-18:2005 Note 2.1	Date expired (21.3.2010)
CEN	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 (ISO 11135-1:2007)	9.8.2007	EN 550:1994 Note 2.1	Date expired (31.5.2010)
CEN	EN ISO 11137-1:2006 Sterilization of health care products - Radiation - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices (ISO 11137-1:2006)	7.9.2006	EN 552:1994 Note 2.1	Date expired (30.4.2009)
CEN	EN ISO 11137-2:2007 Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose (ISO 11137-2:2006, corrected version 2006-08-01)	9.8.2007		
	EN ISO 11137-2:2007/AC:2009	2.12.2009		
CEN	EN ISO 11138-2:2009 Sterilization of health care products - Biological indicators - Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138-2:2006)	2.12.2009	EN ISO 11138-2:2006 Note 2.1	Date expired (21.3.2010)
CEN	EN ISO 11138-3:2009 Sterilization of health care products - Biological indicators - Part 3: Biological indicators for moist heat sterilization processes (ISO 11138-3:2006)	2.12.2009	EN ISO 11138-3:2006 Note 2.1	Date expired (21.3.2010)

(1)	(2)	(3)	(4)	(5)
CEN	EN ISO 11140-1:2009 Sterilization of health care products - Chemical indicators - Part 1: General requirements (ISO 11140-1:2005)	2.12.2009	EN ISO 11140-1:2005 Note 2.1	Date expired (21.3.2010)
CEN	EN ISO 11607-1:2009 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006)	2.12.2009	EN ISO 11607-1:2006 Note 2.1	Date expired (21.3.2010)
CEN	EN ISO 11737-1:2006 Sterilization of medical devices - Microbiological methods - Part 1: Determination of a population of microorganisms on products (ISO 11737-1:2006)	7.9.2006	EN 1174-2:1996 EN 1174-1:1996 EN 1174-3:1996 Note 2.1	Date expired (31.10.2006)
	EN ISO 11737-1:2006/AC:2009	2.12.2009		
CEN	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 (ISO 11737-2:2009)	7.7.2010		
CEN	EN ISO 13408-1:2011 Aseptic processing of health care products - Part 1: General requirements (ISO 13408-1:2008)	19.8.2011	EN 13824:2004 Note 2.1	Date expired (31.12.2011)
CEN	EN ISO 13408-2:2011 Aseptic processing of health care products - Part 2: Filtration (ISO 13408-2:2003)	19.8.2011	EN 13824:2004 Note 2.1	Date expired (31.12.2011)
CEN	EN ISO 13408-3:2011 Aseptic processing of health care products - Part 3: Lyophilization (ISO 13408-3:2006)	19.8.2011	EN 13824:2004 Note 2.1	Date expired (31.12.2011)
CEN	EN ISO 13408-4:2011 Aseptic processing of health care products - Part 4: Clean-in-place technologies (ISO 13408-4:2005)	19.8.2011	EN 13824:2004 Note 2.1	Date expired (31.12.2011)
CEN	EN ISO 13408-5:2011 Aseptic processing of health care products - Part 5: Sterilization in place (ISO 13408-5:2006)	19.8.2011	EN 13824:2004 Note 2.1	Date expired (31.12.2011)
CEN	EN ISO 13408-6:2011 Aseptic processing of health care products - Part 6: Isolator systems (ISO 13408-6:2005)	19.8.2011	EN 13824:2004 Note 2.1	Date expired (31.12.2011)
CEN	EN ISO 13485:2003 Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2003)	2.4.2004	EN ISO 13488:2000 EN ISO 13485:2000 Note 2.1	Date expired (31.7.2009)
	EN ISO 13485:2003/AC:2009	7.7.2010		
CEN	EN ISO 14155:2011 Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2011)	27.4.2012	EN ISO 14155:2011 Note 2.1	30.4.2012
CEN	EN ISO 14155-1:2009 Clinical investigation of medical devices for human subjects - Part 1: General requirements (ISO 14155-1:2003)	7.7.2010	EN ISO 14155-1:2003 Note 2.1	Date expired (21.3.2010)
CEN	EN ISO 14155-2:2009 Clinical investigation of medical devices for human subjects - Part 2: Clinical investigation plans (ISO 14155-2:2003)	7.7.2010	EN ISO 14155-2:2003 Note 2.1	Date expired (21.3.2010)
CEN	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 (ISO 14937:2009)	7.7.2010	EN ISO 14937:2000 Note 2.1	Date expired (21.3.2010)
CEN	EN ISO 14971:2009 Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)	7.7.2010	EN ISO 14971:2007 Note 2.1	Date expired (21.3.2010)

(1)	(2)	(3)	(4)	(5)
CEN	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 (ISO 17665-1:2006)	15.11.2006	EN 554:1994 Note 2.1	Date expired (31.8.2009)
CEN	EN 45502-1:1997 Active implantable medical devices - Part 1: General requirements for safety, marking and information to be provided by the manufacturer	27.8.1998		
CEN	EN 45502-2-1:2004 Active implantable medical devices - Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (cardiac pacemakers)	24.6.2005		
CEN	EN 45502-2-3:2010 Active implantable medical devices - Part 2-3: Particular requirements for cochlear and auditory brainstem implant systems	7.7.2010		
Cenelec	EN 45502-1:1997 Active implantable medical devices - Part 1: General requirements for safety, marking and information to be provided by the manufacturer (*)	27.8.1998		
Cenelec	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) (*)	8.7.2004		
Cenelec	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) (*)	27.11.2008		
	EN 45502-2-2:2008/AC:2009	18.1.2011		
Cenelec	EN 45502-2-3:2010 Active implantable medical devices - Part 2-3: Particular requirements for cochlear and auditory brainstem implant systems (*)	18.1.2011		
Cenelec	EN 60601-1:1990 Medical electrical equipment - Part 1: General requirements for safety IEC 60601-1:1988	23.8.1996		
	EN 60601-1:1990/A1:1993 IEC 60601-1:1988/A1:1991	23.8.1996	Note 3	Date expired (7.7.2010)
	EN 60601-1:1990/A2:1995 IEC 60601-1:1988/A2:1995 (*)	23.8.1996	Note 3	Date expired (7.7.2010)
	EN 60601-1:1990/AC:1994	18.1.2011		
Cenelec	EN 60601-1:2006 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60601-1:2005 (*)	27.11.2008	EN 60601-1:1990 and its amendments Note 2.1	1.6.2012
	EN 60601-1:2006/AC:2010	18.1.2011		
Cenelec	EN 60601-1-6:2010 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability IEC 60601-1-6:2010 (*)	18.1.2011		

(1)	(2)	(3)	(4)	(5)
Cenelec	EN 62304:2006 Medical device software - Software life-cycle processes IEC 62304:2006 (*)	27.11.2008		
	EN 62304:2006/AC:2008	18.1.2011		

(1) ESO: European Standards Organisation:
— CEN: Avenue Marnix 17, 1000 Bruxelles/Brussel, BELGIQUE/BELGIË, Tel. +32 25500811; fax +32 25500819 (http://www.cen.eu)
— Cenelec: Avenue Marnix 17, 1000 Bruxelles/Brussel, BELGIQUE/BELGIË, Tel. +32 25196871; fax +32 25196919 (http://www.cenelec.eu)
— ETSI: 650 route des Lucioles, 06921 Sophia Antipolis, FRANCE, Tel. +33 492944200; fax +33 493654716 (http://www.etsi.eu)
(*) This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

Note 1: Generally the date of cessation of presumption of conformity will be the date of withdrawal ('dow'), set by the European Standardisation Organisation, but attention of users of these standards is drawn to the fact that in certain exceptional cases this can be otherwise.

Note 2.1: The new (or amended) standard has the same scope as the superseded standard. On the date stated, the superseded standard ceases to give presumption of conformity with the essential requirements of the directive.

Note 2.2: The new standard has a broader scope than the superseded standard. On the date stated the superseded standard ceases to give presumption of conformity with the essential requirements of the directive.

Note 2.3: The new standard has a narrower scope than the superseded standard. On the date stated the (partially) superseded standard ceases to give presumption of conformity with the essential requirements of the directive for those products that fall within the scope of the new standard. Presumption of conformity with the essential requirements of the directive for products that still fall within the scope of the (partially) superseded standard, but that do not fall within the scope of the new standard, is unaffected.

Note 3: In case of amendments, the referenced standard is EN CCCCC:YYYY, its previous amendments, if any, and the new, quoted amendment. The superseded standard (column 3) therefore consists of EN CCCCC:YYYY and its previous amendments, if any, but without the new quoted amendment. On the date stated, the superseded standard ceases to give presumption of conformity with the essential requirements of the directive.

NOTE:

— Any information concerning the availability of the standards can be obtained either from the European Standardisation Organisations or from the national standardisation bodies of which the list is annexed to the Directive 98/34/EC of the European Parliament and Council (1) amended by the Directive 98/48/EC (2).

— Harmonised standards are adopted by the European Standardisation Organisations in English (CEN and Cenelec also publish in French and German). Subsequently, the titles of the harmonised standards are translated into all other required official languages of the European Union by the National Standards Bodies. The European Commission is not responsible for the correctness of the titles which have been presented for publication in the Official Journal.

— Publication of the references in the *Official Journal of the European Union* does not imply that the standards are available in all the Community languages.

— This list replaces all the previous lists published in the *Official Journal of the European Union*. The Commission ensures the updating of this list.

— More information about harmonised standards on the Internet at

http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/index_en.htm

(1) OJ L 204, 21.7.1998, p. 37.
(2) OJ L 217, 5.8.1998, p. 18.