EU DECLARATION OF CONFORMITY

OFFICIAL JOURNAL OF ACTIVE IMPLANTABLE MEDICAL DEVICES DIRECTIVE (90/385/EEC)

EU DECLARATION OF CONFORMITY

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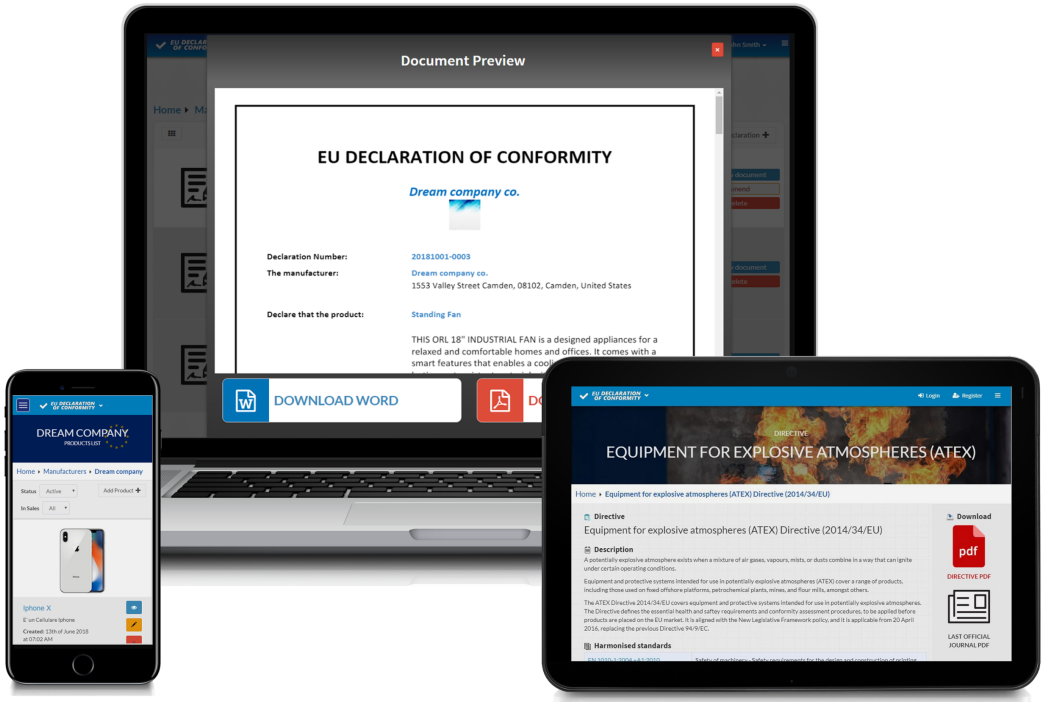

Commission communication in the framework of the implementation of Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices

(Publication of titles and references of harmonised standards under Union harmonisation legislation)

(Text with EEA relevance)

(2017/C 389/02)

ESO ([1])	Reference and title of the standard (and reference document)	First publication OJ	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard Note 1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	30.4.2002
	EN 556-1:2001/AC:2006	15.11.2006		
CEN	EN 556-2:2015 Sterilization of medical devices — Requirements for medical devices to be designated 'STERILE' — Part 2: Requirements for aseptically processed medical devices	13.5.2016	EN 556-2:2003 Note 2.1	30.6.2016
CEN	EN 1041:2008 Information supplied by the manufacturer of medical devices	19.2.2009	EN 1041:1998 Note 2.1	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	21.3.2010
	EN ISO 10993-1:2009/AC:2010	18.1.2011		
CEN	EN ISO 10993-3:2014 Biological evaluation of medical devices — Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity (ISO 10993-3:2014)	10.7.2015		
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	21.3.2010

(1)	(2)	(3)	(4)	(5)
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	31.12.2009
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	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	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	21.3.2010
CEN	EN ISO 10993-12:2012 Biological evaluation of medical devices — Part 12: Sample preparation and reference materials (ISO 10993-12:2012)	24.1.2013	EN ISO 10993-12:2009 Note 2.1	31.1.2013
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	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	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	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	21.3.2010

(1)	(2)	(3)	(4)	(5)
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	31.5.2010
CEN	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 (ISO 11137-1:2006, including Amd 1:2013)	13.5.2016	EN ISO 11137-1:2006 Note 2.1	30.6.2016
CEN	EN ISO 11137-2:2015 Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose (ISO 11137-2:2013)	13.5.2016	EN ISO 11137-2:2013 Note 2.1	30.6.2016
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	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	21.3.2010
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	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	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 1174-1:1996 EN 1174-2:1996 EN 1174-3:1996 Note 2.1	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		

(1)	(2)	(3)	(4)	(5)
CEN	EN ISO 13408-1:2015 Aseptic processing of health care products — Part 1: General requirements (ISO 13408-1:2008, including Amd 1:2013)	13.5.2016	EN ISO 13408-1:2011 Note 2.1	30.6.2016
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	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	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	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	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	31.12.2011
CEN	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)	13.5.2016		
CEN	EN ISO 13485:2016 Medical devices — Quality management systems — Requirements for regulatory purposes (ISO 13485:2016)	This is the first publication	EN ISO 13485:2012 Note 2.1	31.3.2019
	EN ISO 13485:2016/AC:2016	This is the first publication		
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
	EN ISO 14155:2011/AC:2011	This is the first publication		
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	21.3.2010

(1)	(2)	(3)	(4)	(5)
CEN	EN ISO 14971:2012 Medical devices — Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)	30.8.2012	EN ISO 14971:2009 Note 2.1	30.8.2012
CEN	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 (ISO 15223-1:2016, Corrected version 2016-12-15)	This is the first publication	EN 980:2008 Note 2.1	31.12.2017
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	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		
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		

(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

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		

(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

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		

(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

(1)	(2)	(3)	(4)	(5)
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 + A13:1996 + A1:1993 + A2:1995 Note 2.1	1.6.2012
	EN 60601-1:2006/AC:2010	18.1.2011		
	EN 60601-1:2006/A1:2013 IEC 60601-1:2005/A1:2012	10.7.2015	Note 3	31.12.2017

Addendum to Note 1 and Note 3 concerning dates of cessation of presumption of conformity when applying EN 60601-1:2006.
The date of cessation of presumption of conformity when applying EN 60601-1:2006 is 31.12.2017. However the Annex ZZ to EN 60601-1:2006 ceases to specify the presumption of conformity with the Essential Requirements of Directive 90/385/EEC on 31.12.2015. As from 1.1.2016, only the clauses and sub-clauses of EN 60601-1:2006 corresponding to the clauses and sub-clauses referred to in Annex ZZ to EN 60601-1:2006/A1:2013 provide presumption of conformity with the Essential Requirements of Directive 90/385/EEC, to the extent indicated in the Annex ZZ to EN 60601-1:2006/A1:2013.

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		

(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

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		

(*): This European Standard does not necessarily cover the requirements introduced by Directive 2007/47/EC.

([1]) ESO: European standardisation organisation:
— CEN: Avenue Marnix/Marnixlaan 17, 1000 Bruxelles/Brussel, BELGIQUE/BELGIË; tel. +32 25500811; fax +32 25500819 (http://www.cen.eu)
— Cenelec: Avenue Marnix/Marnixlaan 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)

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 or other requirements of the relevant Union legislation.

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 or other requirements of the relevant Union legislation.

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 or other requirements of the relevant Union legislation for those products or services that fall within the scope of the new standard. Presumption of conformity with the essential or other requirements of the relevant Union legislation for products or services 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 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 or other requirements of the relevant Union legislation.

NOTE:

— Any information concerning the availability of the standards can be obtained either from the European standardisation organisations or from the national standardisation bodies the list of which is published in the *Official Journal of the European Union* according to Article 27 of the Regulation (EU) No 1025/2012 ([1]).

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

— References to Corrigenda '…/AC:YYYY' are published for information only. A Corrigendum removes printing, linguistic or similar errors from the text of a standard and may relate to one or more language versions (English, French and/or German) of a standard as adopted by a European standardisation organisation.

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

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

— More information about harmonised standards and other European standards on the Internet at:

http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/index_en.htm

([1]) OJ C 338, 27.9.2014, p. 31.