NOTICES FROM MEMBER STATES

Commission communication in the framework of the implementation of the Council Directive 90/385/EEC 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)

(2009/C 41/05)

ESO [1]	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard (Note 1)
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 EN 556-1:2001/AC:2006	EN 556:1994 + A1:1998	Date expired (30.4.2002)
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	—	
CEN	EN 980:2008 Symbols for use in the labelling of medical devices	EN 980:2003	31.5.2010
CEN	EN 1041:2008 Information supplied by the manufacturer of medical devices	EN 1041:1998	31.8.2011
CEN	EN ISO 10993-1:2003 Biological evaluation of medical devices — Part 1: Evaluation and testing (ISO 10993-1:2003)	—	
CEN	EN ISO 10993-4:2002 Biological evaluation of medical devices — Part 4: Selection of tests for interactions with blood (ISO 10993-4:2002) EN ISO 10993-4:2002/A1:2006	EN 30993-4:1993 Note 3	Date expired (30.4.2003) Date expired (31.1.2007)
CEN	EN ISO 10993-5:1999 Biological evaluation of medical devices — Part 5: Tests for *in vitro* cytotoxicity (ISO 10993-5:1999)	EN 30993-5:1994	Date expired (30.11.1999)
CEN	EN ISO 10993-6:2007 Biological evaluation of medical devices — Part 6: Tests for local effects after implantation (ISO 10993-6:2007)	EN 30993-6:1994	Date expired (31.10.2007)
CEN	EN ISO 10993-9:1999 Biological evaluation of medical devices — Part 9: Framework for identification and quantification of potential degradation products (ISO 10993-9:1999)	—	

ESO ([1])	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard (Note 1)
CEN	EN ISO 10993-10:2002 Biological evaluation of medical devices — Part 10: Tests for irritation and delayed-type hypersensitivity (ISO 10993-10:2002)	EN ISO 10993-10:1995	Date expired (31.3.2003)
	EN ISO 10993-10:2002/A1:2006	Note 3	Date expired (31.1.2007)
CEN	EN ISO 10993-11:2006 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity (ISO 10993-11:2006)	EN ISO 10993-11:1995	Date expired (28.2.2007)
CEN	EN ISO 10993-12:2007 Biological evaluation of medical devices — Part 12: Sample preparation and reference materials (ISO 10993-12:2007)	EN ISO 10993-12:2004	Date expired (31.5.2008)
CEN	EN ISO 10993-13:1998 Biological evaluation of medical devices — Part 13: Identification and quantification of degradation products from polymeric medical devices (ISO 10993-13:1998)	—	
CEN	EN ISO 10993-16:1997 Biological evaluation of medical devices — Part 16: Toxicokinetic study design for degradation products and leachables (ISO 10993-16:1997)	—	
CEN	EN ISO 10993-17:2002 Biological evaluation of medical devices — Part 17: Establishment of allowable limits for leachable substances (ISO 10993-17:2002)	—	
CEN	EN ISO 10993-18:2005 Biological evaluation of medical devices — Part 18: Chemical characterization of materials (ISO 10993-18:2005)	—	
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)	EN 550:1994	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)	EN 552:1994	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 1.8.2006)	—	
CEN	EN ISO 11138-2:2006 Sterilization of health care products — Biological indicators — Part 2: Biological indicators for ethylene oxide sterilization processes (ISO 11138-2:2006)	—	
CEN	EN ISO 11138-3:2006 Sterilization of health care products — Biological indicators — Part 3: Biological indicators for moist heat sterilization processes (ISO 11138-3:2006)	—	
CEN	EN ISO 11140-1:2005 Sterilization of health care products — Chemical indicators — Part 1: General requirements (ISO 11140-1:2005)	—	

ESO (1)	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard (Note 1)
CEN	EN ISO 11607-1:2006 Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems (ISO 11607-1:2006)	EN 868-1:1997	Date expired (30.4.2007)
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)	EN 1174-1:1996 EN 1174-2:1996 EN 1174-3:1996	Date expired (31.10.2006)
CEN	EN ISO 13485:2003 Medical devices — Quality management systems — Requirements for regulatory purposes (ISO 13485:2003) EN ISO 13485:2003/AC:2007	EN ISO 13485:2000 EN ISO 13488:2000	31.7.2009
CEN	EN 13824:2004 Sterilization of medical devices — Aseptic processing of liquid medical devices — Requirements	—	
CEN	EN ISO 14155-1:2003 Clinical investigation of medical devices for human subjects — Part 1: General requirements (ISO 14155-1:2003)	EN 540:1993	Date expired (31.8.2003)
CEN	EN ISO 14155-2:2003 Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans (ISO 14155-2:2003)	—	
CEN	EN ISO 14937:2000 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 14937:2000)	—	
CEN	EN ISO 14971:2007 Medical devices — Application of risk management to medical devices (ISO 14971:2007)	EN ISO 14971:2000	31.3.2010
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)	EN 554:1994	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	—	
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)	—	

(1) ESO: European Standardisation Organisation:
— CEN: rue de Stassart 36, B-1050 Brussels, tel. (32-2) 550 08 11; fax (32-2) 550 08 19 (http://www.cen.eu),
— Cenelec: rue de Stassart 35, B-1050 Brussels, tel. (32-2) 519 68 71; fax (32-2) 519 69 19 (http://www.cenelec.org),
— ETSI: 650, route des Lucioles, F-06921 Sophia Antipolis, tel. (33) 492 94 42 00; fax (33) 493 65 47 16 (http://www.etsi.org).

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 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 of the Council ([1]) amended by the Directive 98/48/EC ([2]),

— 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/newapproach/standardization/harmstds/

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