

Commission communication in the framework of the implementation of 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

(2006/C 129/02)

(Text with EEA relevance)

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

ESO (*)	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard Note 1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 550:1994 Sterilization of medical devices — Validation and routine control of ethylene oxide sterilization	—	
CEN	EN 552:1994 Sterilization of medical devices — Validation and routine control of sterilization by irradiation	—	
CEN	EN 554:1994 Sterilization of medical devices — Validation and routine control of sterilization by moist heat	—	
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 556:1994 + 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 868-1:1997 Packaging materials and systems for medical devices which are to be sterilized — Part 1: General requirements and test methods	—	
CEN	EN 980:2003 Graphical symbols for use in the labelling of medical devices	EN 980:1996	Date expired (31.10.2003)
CEN	EN 1041:1998 Information supplied by the manufacturer with medical devices	—	
CEN	EN 1174-1:1996 Sterilization of medical devices — Estimation of the population of micro-organisms on product — Part 1: Requirements	—	
CEN	EN 1174-2:1996 Sterilization of medical devices — Estimation of the population of micro-organisms on product — Part 2: Guidance	—	
CEN	EN 1174-3:1996 Sterilization of medical devices — Estimation of the population of micro-organisms on product — Part 3: Guide to the methods for validation of microbiological techniques	—	
CEN	EN ISO 10993-1:2003 Biological evaluation of medical devices — Part 1: Evaluation and testing (ISO 10993-1:2003)	—	

ESO (*)	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presump- tion of conformity of super- seded standard Note 1
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 30993-4:1993	Date expired (30.4.2003)
CEN	EN ISO 10993-5:1999 Biological evaluation of medical devices — Part 5: Tests for in vitro cyto- toxicity (ISO 10993-5:1999)	EN 30993-5:1994	Date expired (30.11.1999)
CEN	EN ISO 10993-9:1999 Biological evaluation of medical devices — Part 9: Framework for identi- fication and quantification of potential degradation products (ISO 10993-9:1999)	—	
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)
CEN	EN ISO 10993-11:1995 Biological evaluation of medical devices — Part 11: Tests for systemic toxicity (ISO 10993-11:1993)	—	
CEN	EN ISO 10993-12:2004 Biological evaluation of medical devices — Part 12: Sample preparation and reference materials (ISO 10993-12:2002)	EN ISO 10993-12:1996	Date expired (31.5.2005)
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 characteri- zation of materials (ISO 10993-18:2005)	—	
CEN	EN ISO 11140-1:2005 Sterilization of health care products — Chemical indicators — Part 1: General requirements (ISO 11140-1:2005)	—	
CEN	EN ISO 13485:2003 Medical devices — Quality management systems — Requirements for regulatory purposes (ISO 13485:2003)	EN ISO 13485:2000 EN ISO 13488:2000	31.7.2006
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)

ESO ⁽¹⁾	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presump- tion of conformity of super- seded standard Note 1
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 14971:2000 Medical devices — Application of risk management to medical devices (ISO 14971:2000) EN ISO 14971:2000/A1:2003	EN 1441:1997 Note 3	Date expired (31.3.2004) Date expired (31.3.2004)
CEN	EN 30993-6:1994 Biological evaluation of medical devices — Part 6: Tests for local effects after implantation (ISO 10993-6:1994)	—	
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.cenorm.be>)

— 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 CCCC:YYYY, its previous amendments, if any, and the new, quoted amendment. The superseded standard (column 3) therefore consists of EN CCCC: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 Directive 98/34/EC ⁽¹⁾ of the European Parliament and of the Council amended by 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.

More information about harmonised standards on the Internet at:

<http://europa.eu.int/comm/enterprise/newapproach/standardization/harmstds/>

⁽¹⁾ OJ L 204, 21.7.1998, p. 37.

⁽²⁾ OJ L 217, 5.8.1998, p. 18.