Commission communication in the framework of the implementation of the Directive 98/79/EC of the European Parliament and of the Council on *in vitro* diagnostic medical devices

(Text with EEA relevance)

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

(2009/C 41/07)

ESO ([1])	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard (Note 1)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 375:2001 Information supplied by the manufacturer with *in vitro* diagnostic reagents for professional use	—	
CEN	EN 376:2002 Information supplied by the manufacturer with *in vitro* diagnostic reagents for self-testing	—	
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 591:2001 Instructions for use for *in vitro* diagnostic instruments for professional use	—	
CEN	EN 592:2002 Instructions for use for *in vitro* diagnostic instruments for self-testing	—	
CEN	EN 980:2008 Symbols for use in the labelling of medical devices	EN 980:2003	31.5.2010
CEN	EN 12286:1998 *In vitro* diagnostic medical devices — Measurement of quantities in samples of biological origin — Presentation of reference measurement procedures EN 12286:1998/A1:2000	— Note 3	 Date expired (24.11.2000)
CEN	EN 12287:1999 *In vitro* diagnostic medical devices — Measurement of quantities in samples of biological origin — Description of reference materials	—	
CEN	EN 12322:1999 *In vitro* diagnostic medical devices — Culture media for microbiology — Performance criteria for culture media EN 12322:1999/A1:2001	— Note 3	 Date expired (30.4.2002)
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 13532:2002 General requirements for *in vitro* diagnostic medical devices for self-testing	—	

ESO (1)	Reference and title of the harmonised standard (and reference document)	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard (Note 1)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 13612:2002 Performance evaluation of *in vitro* diagnostic medical devices	—	
CEN	EN 13640:2002 Stability testing of *in vitro* diagnostic reagents	—	
CEN	EN 13641:2002 Elimination or reduction of risk of infection related to *in vitro* diagnostic reagents	—	
CEN	EN 13975:2003 Sampling procedures used for acceptance testing of *in vitro* diagnostic medical devices — Statistical aspects	—	
CEN	EN 14136:2004 Use of external quality assessment schemes in the assessment of the performance of *in vitro* diagnostic examination procedures	—	
CEN	EN 14254:2004 *In vitro* diagnostic medical devices — Single-use receptacles for the collection of specimens, other than blood, from humans	—	
CEN	EN 14820:2004 Single-use containers for human venous blood specimen collection	—	
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 15197:2003 *In vitro* diagnostic test systems — Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus (ISO 15197:2003)	—	
CEN	EN ISO 15225:2000 Nomenclature — Specification for a nomenclature system for medical devices for the purpose of regulatory data exchange (ISO 15225:2000)	—	
CEN	EN ISO 17511:2003 *In vitro* diagnostic medical devices — Measurement of quantities in biological samples — Metrological traceability of values assigned to calibrators and control materials (ISO 17511:2003)	—	
CEN	EN ISO 18153:2003 *In vitro* diagnostic medical devices — Measurement of quantities in biological samples — Metrological traceability of values for catalytic concentration of enzymes assigned to calibrators and control materials (ISO 18153:2003)	—	
CEN	EN ISO 20776-1:2006 Clinical laboratory testing and *in vitro* diagnostic test systems — Susceptibility testing of infectious agents and evaluation of performance of antimicrobial susceptibility test devices — Part 1: Reference method for testing the *in vitro* activity of antimicrobial agents against rapidly growing aerobic bacteria involved in infectious diseases (ISO 20776-1:2006)	—	

(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/

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