

## NOTICES FROM MEMBER STATES

**Commission communication in the framework of the implementation of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices****(Text with EEA relevance)***(Publication of titles and references of harmonised standards under the directive)**(2009/C 95/04)*

ESO <sup>(1)</sup>	Reference and title of the harmonised standard (and reference document)	First publication OJ	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard Note 1
Cenelec	EN 61010-2-101:2002 Safety requirements for electrical equipment for measurement, control, and laboratory use Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment IEC 61010-2-101:2002 (Modified)	17.12.2002		
Cenelec	EN 61326-2-6:2006 Electrical equipment for measurement, control and laboratory use — EMC requirements Part 2-6: Particular requirements — In vitro diagnostic (IVD) medical equipment IEC 61326-2-6:2005	27.11.2008		
Cenelec	EN 62304:2006 Medical device software — Software life-cycle processes IEC 62304:2006	27.11.2008		
Cenelec	EN 62366:2008 Medical devices — Application of usability engineering to medical devices IEC 62366:2007	27.11.2008		
CEN	EN 375:2001 Information supplied by the manufacturer with in vitro diagnostic reagents for professional use	31.7.2002		
CEN	EN 376:2002 Information supplied by the manufacturer with in vitro diagnostic reagents for self-testing	31.7.2002		

ESO <sup>(1)</sup>	Reference and title of the harmonised standard (and reference document)	First publication OJ	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard Note 1
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	31.7.2002  15.11.2006	EN 556:1994 A1:1998 Note 2.1	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	9.8.2007		
CEN	EN 591:2001 Instructions for use for in vitro diagnostic instruments for professional use	31.7.2002		
CEN	EN 592:2002 Instructions for use for in vitro diagnostic instruments for self-testing	31.7.2002		
CEN	EN 980:2008 Symbols for use in the labelling of medical devices	23.7.2008	EN 980:2003 Note 2.1	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	10.8.1999  14.11.2001	  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	14.10.2000		
CEN	EN 12322:1999 In vitro diagnostic medical devices — Culture media for microbiology — Performance criteria for culture media  EN 12322:1999/A1:2001	9.10.1999  31.7.2002	  Note 3	  Date expired (30.4.2002)

ESO <sup>(1)</sup>	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
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	31.7.2009
	EN ISO 13485:2003/AC:2007	9.8.2007		
CEN	EN 13532:2002 General requirements for in vitro diagnostic medical devices for self-testing	17.12.2002		
CEN	EN 13612:2002 Performance evaluation of in vitro diagnostic medical devices	17.12.2002		
CEN	EN 13640:2002 Stability testing of in vitro diagnostic reagents	17.12.2002		
CEN	EN 13641:2002 Elimination or reduction of risk of infection related to in vitro diagnostic reagents	17.12.2002		
CEN	EN 13975:2003 Sampling procedures used for acceptance testing of in vitro diagnostic medical devices — Statistical aspects	21.11.2003		
CEN	EN 14136:2004 Use of external quality assessment schemes in the assessment of the performance of in vitro diagnostic examination procedures	15.11.2006		
CEN	EN 14254:2004 In vitro diagnostic medical devices — Single-use receptacles for the collection of specimens, other than blood, from humans	28.4.2005		
CEN	EN 14820:2004 Single-use containers for human venous blood specimen collection	28.4.2005		
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)	31.7.2002		

ESO <sup>(1)</sup>	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
CEN	EN ISO 14971:2007 Medical devices — Application of risk management to medical devices (ISO 14971:2007)	9.8.2007	EN ISO 14971:2000 Note 2.1	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)	28.4.2005		
CEN	EN ISO 15225:2000 Nomenclature — Specification for a nomenclature system for medical devices for the purpose of regulatory data exchange (ISO 15225:2000)	31.7.2002		
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)	28.4.2005		
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)	21.11.2003		
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)	9.8.2007		

<sup>(1)</sup> ESO: European Standards Organisation:

- CEN: Avenue Marnix 17, B-1000, Brussels, Tel.+32 2 5500811; fax +32 2 5500819 (<http://www.cen.eu>)
- CENELEC: Avenue Marnix 17, B-1000, Brussels, Tel.+32 2 5196871; fax +32 2 5196919 (<http://www.cenelec.org>)
- ETSI: 650, route des Lucioles, F-06921 Sophia Antipolis, Tel.+33 492 944200; fax +33 493 654716, (<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 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 amended by the Directive 98/48/EC.
- 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. [this note has only to be included in the case of a consolidated list]
- More information about harmonised standards on the Internet at:

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

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