

(1)	(2)	(3)	(4)	(5)
CEN	EN ISO 15193:2009 In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for content and presentation of reference measurement procedures (ISO 15193:2009)	7.7.2010		
CEN	EN ISO 15194:2009 In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for certified reference materials and the content of supporting documentation (ISO 15194:2009)	7.7.2010		
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		
	EN ISO 15197:2003/AC:2005	2.12.2009		
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 18113-1:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 1: Terms, definitions and general requirements (ISO 18113-1:2009)	27.4.2012	EN ISO 18113-1:2009 Note 2.1	Date expired (30.4.2012)
CEN	EN ISO 18113-2:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use (ISO 18113-2:2009)	27.4.2012	EN ISO 18113-2:2009 Note 2.1	Date expired (30.4.2012)
CEN	EN ISO 18113-3:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 3: In vitro diagnostic instruments for professional use (ISO 18113-3:2009)	27.4.2012	EN ISO 18113-3:2009 Note 2.1	Date expired (30.4.2012)
CEN	EN ISO 18113-4:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 4: In vitro diagnostic reagents for self-testing (ISO 18113-4:2009)	27.4.2012	EN ISO 18113-4:2009 Note 2.1	Date expired (30.4.2012)
CEN	EN ISO 18113-5:2011 In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 5: In vitro diagnostic instruments for self-testing (ISO 18113-5:2009)	27.4.2012	EN ISO 18113-5:2009 Note 2.1	Date expired (30.4.2012)
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		

(1)	(2)	(3)	(4)	(5)
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		
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		
	EN 62304:2006/AC:2008	18.1.2011		
Cenelec	EN 62366:2008 Medical devices - Application of usability engineering to medical devices IEC 62366:2007	27.11.2008		

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

- CEN: Avenue Marnix 17, 1000 Bruxelles/Brussel, BELGIQUE/BELGIË, Tel. +32 25500811; fax +32 25500819 (<http://www.cen.eu>)
- Cenelec: Avenue Marnix 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 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 CCCC:YYYY, its previous amendments, if any, and the new, quoted amendment. The superseded standard 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 the Directive 98/34/EC of the European Parliament and Council amended by the Directive 98/48/EC.
  - Harmonised standards are adopted by the European Standardisation Organisations in English (CEN and Cenelec also publish in French and German). Subsequently, the titles of the harmonised standards are translated into all other required official languages of the European Union by the National Standards Bodies. The European Commission is not responsible for the correctness of the titles which have been presented for publication in the Official Journal.
  - 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/policies/european-standards/harmonised-standards/index\\_en.htm](http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/index_en.htm)
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