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

(Publication of titles and references of harmonised standards under Union harmonisation legislation)

(Text with EEA relevance)

(2015/C 226/03)

ESO [1]	Reference and title of the standard (and reference document)	First publication OJ	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard Note 1
(1)	(2)	(3)	(4)	(5)
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	31.7.2002	EN 556:1994 + A1:1998 Note 2.1	Date expired (30.4.2002)
	EN 556-1:2001/AC:2006	15.11.2006		
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 980:2008 Symbols for use in the labelling of medical devices	23.7.2008	EN 980:2003 Note 2.1	Date expired (31.5.2010)
CEN	EN ISO 11137-2:2013 Sterilization of health care products — Radiation — Part 2: Establishing the sterilization dose (ISO 11137-2:2013)	16.1.2015	EN ISO 11137-2:2012 Note 2.1	Date expired (30.11.2014)
CEN	EN ISO 11737-2:2009 Sterilization of medical devices — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process (ISO 11737-2:2009)	7.7.2010		
CEN	EN 12322:1999 In vitro diagnostic medical devices — Culture media for microbiology — Performance criteria for culture media	9.10.1999		
	EN 12322:1999/A1:2001	31.7.2002	Note 3	Date expired (30.4.2002)

(1)	(2)	(3)	(4)	(5)
CEN	EN ISO 13408-1:2011 Aseptic processing of health care products — Part 1: General requirements (ISO 13408-1:2008)	19.8.2011		
	EN ISO 13408-1:2011/A1:2013	16.1.2015	Note 3	Date expired (30.11.2014)
CEN	EN ISO 13408-2:2011 Aseptic processing of health care products — Part 2: Filtration (ISO 13408-2:2003)	19.8.2011		
CEN	EN ISO 13408-3:2011 Aseptic processing of health care products — Part 3: Lyophilization (ISO 13408-3:2006)	19.8.2011		
CEN	EN ISO 13408-4:2011 Aseptic processing of health care products — Part 4: Clean-in-place technologies (ISO 13408-4:2005)	19.8.2011		
CEN	EN ISO 13408-5:2011 Aseptic processing of health care products — Part 5: Sterilization in place (ISO 13408-5:2006)	19.8.2011		
CEN	EN ISO 13408-6:2011 Aseptic processing of health care products — Part 6: Isolator systems (ISO 13408-6:2005)	19.8.2011		
CEN	EN ISO 13485:2012 Medical devices — Quality management systems — Requirements for regulatory purposes (ISO 13485:2003)	30.8.2012	EN ISO 13485:2003 Note 2.1	Date expired (31.8.2012)
	EN ISO 13485:2012/AC:2012	30.8.2012		
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		
	EN 13612:2002/AC:2002	2.12.2009		
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		

(1)	(2)	(3)	(4)	(5)
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 14937:2009 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 14937:2009)	7.7.2010	EN ISO 14937:2000 Note 2.1	Date expired (30.4.2010)
CEN	EN ISO 14971:2012 Medical devices — Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01)	30.8.2012	EN ISO 14971:2009 Note 2.1	Date expired (30.8.2012)
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		

(1)	(2)	(3)	(4)	(5)
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		
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		

(1)	(2)	(3)	(4)	(5)
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		

([1]) ESO: European standardisation 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.eu)
— 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 or other requirements of the relevant Union legislation.

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 or other requirements of the relevant Union legislation.

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 or other requirements of the relevant Union legislation for those products or services that fall within the scope of the new standard. Presumption of conformity with the essential or other requirements of the relevant Union legislation for products or services 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 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 or other requirements of the relevant Union legislation.

NOTE:

— Any information concerning the availability of the standards can be obtained either from the European standardisation organisations or from the national standardisation bodies the list of which is published in the *Official Journal of the European Union* according to Article 27 of the Regulation (EU) No1025/2012 ([1]).

— Standards are adopted by the European standardisation organisations in English (CEN and Cenelec also publish in French and German). Subsequently, the titles of the standards are translated into all other required official languages of the European Union by the national standardisation bodies. The European Commission is not responsible for the correctness of the titles which have been presented for publication in the Official Journal.

— References to Corrigenda '.../AC:YYYY' are published for information only. A Corrigendum removes printing, linguistic or similar errors from the text of a standard and may relate to one or more language versions (English, French and/or German) of a standard as adopted by a European standardisation organisation.

— Publication of the references in the *Official Journal of the European Union* does not imply that the standards are available in all the official languages of the European Union.

— This list replaces all the previous lists published in the *Official Journal of the European Union*. The European Commission ensures the updating of this list.

— More information about harmonised standards and other European standards on the Internet at

http://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/index_en.htm

([1]) OJ L 316, 14.11.2012, p. 12.