

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 harmonized standards under the directive)

(2008/C 304/05)

ESO ⁽¹⁾	Reference and title of the standard (and reference document)	Reference of the superseded standard	Date of cessation of presumption of conformity of the superseded standard (Note 1)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 <i>in vitro</i> diagnostic (IVD) medical equipment (IEC 61010-2-101:2002 (Modified))	—	—
Cenelec	EN 61326-2-6:2006 Electrical equipment for measurement, control and laboratory use — EMC requirements — Part 2-6: Particular requirements — <i>In vitro</i> diagnostic (IVD) medical equipment (IEC 61326-2-6:2005)	—	—
Cenelec	EN 62304:2006 Medical device software — Software life-cycle processes (IEC 62304:2006)	—	—
Cenelec	EN 62366:2008 Medical devices — Application of usability engineering to medical devices (IEC 62366:2007)	—	—

⁽¹⁾ ESO: European Standardisation Organisation:

- CEN: rue de Stassart/De Stassartstraat 36, B-1050 Brussels, tel. (32-2) 550 08 11, fax (32-2) 550 08 19 (<http://www.cenorm.be>),
- Cenelec: rue de Stassart/De Stassartstraat 35, B-1050 Brussels, tel. (32-2) 519 68 71, fax (32-2) 519 69 19 (<http://www.cenelec.eu>),
- ETSI: 650, route des Lucioles, F-06921 Sophia Antipolis, tel. (33) 492 94 42 12, 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.