NOTICES FROM MEMBER STATES

Commission communication in the framework of the implementation of the Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices

(Text with EEA relevance)

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

(2008/C 304/04)

ESO [1]	Reference and title of the standard (and reference document)	Reference of the superseded standard	Date of cessation of presumption of conformity of the superseded standard (Note 1)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 45502-1:1997 Active implantable medical devices — Part 1: General requirements for safety, marking and information to be provided by the manufacturer	—	—
Cenelec	EN 45502-2-1:2003 Active implantable medical devices — Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (cardiac pacemakers)	—	—
Cenelec	EN 45502-2-2:2008 Active implantable medical devices — Part 2-2: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (includes implantable defibrillators)	—	—
Cenelec	EN 60601-1:1990 Medical electrical equipment — Part 1: General requirements for safety (IEC 60601-1:1988)	—	—
	Amendment A1:1993 to EN 60601-1:1990 (IEC 60601-1:1988/A1:1991)	Note 3	—
	Amendment A2:1995 to EN 60601-1:1990 (IEC 60601-1:1988/A2:1995)	Note 3	—
Cenelec	EN 60601-1:2006 Medical electrical equipment — Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005)	EN 60601-1:1990 and its amendments Note 2.1	—
Cenelec	EN 62304:2006 Medical device software — Software life-cycle processes (IEC 62304:2006)	—	—

[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.

Note 2.1: The new (or amended) standard has the same scope as the superseded standard.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 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.