Commission communication in the framework of the implementation of Council Directive 90/385/EEC of 20 June 1990 in relation to 'Active Implantable Medical Devices' [1] and Council Directive 93/42/EEC of 14 June 1993 in relation to 'Medical Devices' [2]

(2003/C 270/02)

(Text with EEA relevance)

(Publication of titles and references of European harmonised standards under the directive)

ESO [1]	Reference	Title of the harmonised standards
CEN	EN ISO 10993-17:2002	Biological evaluation of medical devices — Part 17: Establishment of allowable limits for leachable substances (ISO 10993-17:2002)
CEN	EN ISO 14155-1:2003	Clinical investigation of medical devices for human subjects — Part 1: General requirements (ISO 14155-1:2003)
CEN	EN ISO 14155-2:2003	Clinical investigation of medical devices for human subjects — Part 2: Clinical investigation plans (ISO 14155-2:2003)

[1] ESO (European standardisation organisations):
— CEN: rue de Stassart 36, B-1050 Brussels, tel. (32-2) 550 08 11, fax (32-2) 550 08 19 (http://www.cenorm.be)
— Cenelec: rue de Stassart 35, B-1050 Brussels, tel. (32-2) 519 68 71, fax (32-2) 519 69 19 (http://www.cenelec.org)
— ETSI: 650, route des Lucioles, F-06921 Sophia Antipolis Cedex, tel. (33-4) 92 94 42 00, fax (33-4) 93 65 47 16 (http://www.etsi.org).

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 [3] of the European Parliament and of the Council of 22 June 1998.

— 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.

— The Commission ensures the updating of this list.

[1] OJ L 189, 20.7.1990, p. 17.

[2] OJ L 169, 12.7.1993, p. 1.

[3] OJ L 204, 21.7.1998, p. 37.