Commission Communication in the framework of the implementation of Council Directive 93/42/EEC of 14 June 1993 in relation to medical devices [1]

(2000/C 293/06)

(Text with EEA relevance)

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

ESO [1]	Reference	Title of the harmonised standards	Year of ratification
CEN	EN 455-3	Medical gloves for single use — Part 3: requirements and testing for biological evaluation	1999
CEN	EN 737-2/A1	Medical gas pipeline systems — Part 2: anaesthetic gas scavenging disposal systems — basic requirements	1998 1999
CEN	EN 737-3/A1	Medical gas pipeline systems — Part 3: pipelines for compressed medical gases and vacuum	1998 1999
CEN	EN 738-2	Pressure regulators for use with medical gases — Part 2: manifold and line pressure regulators	1998
CEN	EN 738-3	Pressure regulators for use with medical gases — Part 3: pressure regulators integrated with cylinder valves	1998
CEN	EN 738-4	Pressure regulators for use with medical gases — Part 4: low-pressure regulators intended for incorporation into medical equipment	1998
CEN	EN 1089-3/A1	Transportable gas cylinders — gas cylinder identification — Part 3: colour coding	1997 1999
CEN	EN 1865	Specifications for stretchers and other patient-handling equipment used in road ambulances	1999
CEN	EN ISO 10079-1	Medical suction equipment — Part 1: electrically powered suction equipment — safety requirements (ISO 10079-1:1999)	1999
CEN	EN ISO 10079-2	Medical suction equipment — Part 2: manually powered suction equipment (ISO 10079-2:1999)	1999
CEN	EN ISO 10079-3	Medical suction equipment — Part 3: suction equipment powered from a vacuum or pressure source (ISO 10079-3:1999)	1999
CEN	EN ISO 10535	Hoists for the transfer of disabled persons — requirements and test methods (ISO 10535:1998)	1998
CEN	EN ISO 10555-1/A1	Sterile, single-use intra-vascular catheters — Part 1: general requirements (ISO 10555-1:1996/Amd 1:1999)	1996 1999
CEN	EN ISO 11990	Optics and optical instruments — lasers and laser-related equipment — determination of laser resistance of tracheal tube shafts (ISO 11990:1999)	1999
CEN	EN 12006-1	Non-active surgical implants — particular requirements for cardiac and vascular implants — Part 1: heart valve substitutes	1999
CEN	EN 12182	Technical aids for disabled persons — general requirements and test methods	1999
CEN	EN 12218	Rail systems for supporting medical equipment	1998
CEN	EN 12470-1	Clinical thermometers — Part 1: metallic liquid-in-glass thermometers with maximum device	2000

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

ESO (1)	Reference	Title of the harmonised standards	Year of ratification
CEN	EN 12470-3	Clinical thermometers — Part 3: performance of compact electrical thermometers (non-predictive and predictive) with maximum device	2000
CEN	EN 13220	Flow-metering devices for connection to terminal units of medical gas pipeline systems	1998

(1) ESO: (European standardisation organisation):
— CEN: rue de Stassart/Stassartstraat 36, B-1050 Brussels; tel. (32-2) 550 08 11, fax (32-2) 550 08 19 (www.cenorm.be);
— Cenelec: rue de Stassart/Stassartstraat 35, B-1050 Brussels; tel. (32-2) 519 68 71, fax (32-2) 519 69 19 (www.cenelec.be);
— ETSI: BP 152, F-06561 Valbonne Cedex, tel. (33-4) 92 94 42 12, fax (33-4) 93 65 47 16 (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 (1) of the European Parliament and of the Council of 22 June 1998.

— publication of the references in the *Official Journal of the European Communities* does not imply that the standards are available in all the Community languages.

— The Commission ensures the updating of this list (2).

(1) OJ L 204, 21.7.1998, p. 37.
(2) OJ C 181, 26.6.1999, p. 4, OJ C 227, 10.8.1999, p. 15, OJ C 288, 9.10.1999, p. 43.

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)

(2000/C 293/07)

(Text with EEA relevance)

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

ESO (1)	Reference	Title of the harmonised standards	Year of ratification
CEN	EN 980/A1	Graphical symbols for use in the labelling of medical devices	1996 1999
CEN	EN 30993-7	Biological evaluation of medical devices — Part 7: ethylene oxide sterilisation residuals (ISO 10993-7:1995)	1995
CEN Cenelec	EN 46003	Quality systems — medical devices — particular requirements for the application of EN ISO 9003	1999

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— Cenelec: rue de Stassart/Stassartstraat 35, B-1050 Brussels; tel. (32-2) 519 68 71, fax (32-2) 519 69 19 (www.cenelec.be);
— ETSI: BP 152, F-06561 Valbonne Cedex, tel. (33-4) 92 94 42 12, fax (33-4) 93 65 47 16 (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 Communities* does not imply that the standards are available in all the Community languages.

— the Commission ensures the updating of this list (4).

(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.
(4) OJ C 181, 26.6.1999, p. 2, OJ C 227, 10.8.1999, p. 15, OJ C 288, 9.10.1999, p. 42.