BT127/DG6582/DV
April 2006

BT BY CORRESPONDENCE – Item 5.4.3 **Deadline: 2006-05-31**

SUBJECT

MDD DIRECTIVE (93/42/EEC)
List of new harmonised standards

BACKGROUND

The document in annex identifies those new harmonised standards, the reference of which should be offered to the Commission in view of their listing in the Official Journal under the heading of Directive 93/42/EEC, the Medical Devices Directive.

The list of standards has been structured in accordance with the format as requested by the Commission and it is the intention to incorporate them into a consolidated list of harmonised standards for subsequent submission to the Commission services.

The MDD Consultant has not objected to the list of standards.

PROPOSED DECISION

BT decided by correspondence to approve the list of new harmonised standards for publication of their references in the Official Journal under the heading of the Medical Devices Directive, and instructed CS to offer the references of the listed harmonised standards to the Commission services for that purpose in the appropriate consolidated presentation format.

JPV/BL

2006-04-26

Commission communication in the framework of the implementation of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices

(Text with EEA relevance)

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

EN

European Standardisation Organisation	Reference and title of the standard (and reference document)	Reference of the superseded standard	Date of cessation of presumption of conformity of the superseded standard Note 1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 60601-1-6:2004 Medical electrical equipment - Part 1-6: General requirements for safety - Collateral standard: Usability (IEC 60601-1-6:2004)	NONE	-
CENELEC	EN 60601-1-8:2004 Medical electrical equipment - Part 1-8: General requirements for safety - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems (IEC 60601-1-8:2003)	NONE	-
CENELEC	EN 60601-2-27:2006 Medical electrical equipment - Part 2-27: Particular requirements for the safety, including essential performance, of electrocardiographic monitoring equipment (IEC 60601-2-27:2005)	EN 60601-2-27:1994 Note 2.1	01.11.2008
CENELEC	Amendment A1:2005 to EN 60601-2-33:2002 Medical electrical equipment - Part 2-33: Particular requirements for the safety of magnetic resonance equipment for medical diagnosis (IEC 60601-2-33:2002/A1:2005)	Note 3	01.11.2008
CENELEC	Amendment A2:2005 to EN 60601-2-37:2001 Medical electrical equipment - Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment (IEC 60601-2-37:2001/A2:2005)	Note 3	01.12.2008

- 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.org)
- 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)