EUROPEAN COMMISSION
ENTERPRISE DIRECTORATE-GENERAL

Single Market : regulatory environment, standardisation and New Approach
Pressure equipment, medical devices, metrology

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M/332 EN

Standardization mandate to CEN/CENELEC concerning a proposed amendment to clarify matters of electrical safety in the application of EN 1970: 2000 "Beds for the disabled"

GENERAL

Several standardization mandates are already issued in the field of medical devices.

- Mandate BC/CEN/CENELEC/09/89 concerns active implantable devices
- Mandate BC/CENELEC/02/89 concerns horizontal aspects of medical devices.
- Mandate BC/CEN/03/023/93-08 is a general mandate to produce level 1, 2 and 3 standards. This mandate is further extended by mandate M/295.
- Mandate BC/CEN/03/91 concerns specifically condoms.
- M/252 covers the specific requirements for In-Vitro diagnostic devices.
- M/320 covering changes to the standard of breast implants.
- M/321 covering the preparation a list of medical device subcategories.

Besides the current draft mandate, which is a specific mandate in the application of the Council Directive 93/42/EEC on Medical Devices,

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another mandate is under preparation regarding the flammability of mattresses and bed bases for medical purposes.

I BACKGROUND

There are currently three European standards regarding the hospital beds and the beds for the disabled. The standards, all of which are published in Official Journal, are the following:

- EN1970 "Adjustable beds for disabled persons – Requirements and test methods" (published in C319, 14th November 2001),
- EN60601-1 "Medical electrical equipment. Part 1: General requirements for safety" (published before November 2001) and
- EN 60601-2-38 entitled "Particular requirements for the safety of electrically operated hospital beds" (published in C319, 14th November 2001).

Whilst EN1970 contains a normative reference to EN60601-1, no explicit reference is made to EN60601-2-38. The experience reported suggests that EN60601-2-38 is not always followed by manufacturers for matters relating to electrical safety when implementing EN1970[1].

II MOTIVATION AND NEEDS

In order to ensure full transparency and clarity on the standards to be taken into consideration in implementing EN1970, it would be appropriate for CEN/CENELEC to issue an amendment to EN1970 by adding a normative reference to EN 60601-2-38 for matters relating to electrical safety. It is also appropriate to further clarify the intentions of EN1970 by indicating that the title "Beds for the disabled" refers to such beds for use both in the hospital environment and for use outside the hospital, e.g. in domestic environment. This can be achieved by adding clarity to the scope to establish that this standard covers beds intended for use either within or outside the hospital environment.

There is a mandate already existing, M/295, which in section II B 6 has requested work on combining all aspects relating to beds for medical purposes into one comprehensive standard (the contents of EN1970 plus the

[1] The Global Medical Device Nomenclature (GMDN) indicates that beds for medical-related purposes are covered by the term "Bed, hospital". This includes beds used by patients and disabled persons in hospitals, institutions and home care. The beds can be designed for resting or for different kind of treatment purposes.

contents of EN60601-2-38). When this single comprehensive standard is published there can be no such confusion in the future.

III STANDARDIZATION MANDATE

CEN and CENELEC are requested to prepare an amendment as soon as possible to clarify standard EN1970 by referencing matters of electrical safety in the manner described, to cover the period until work is completed in combining the contents of EN1970 with EN60601-2-38 as already mandated by the Commission in M/295.

IV EXECUTION OF THE MANDATE

1. An indication of a target date for a draft amendment and for the final adoption, will be provided by CEN/CENELEC.

2. The work will be carried out in close consultation with the Commission, taking into account the fact that the concerned directives are already applied.

3. Within 6 months after the adoption the amended EN harmonized standard will be transposed into national standards. Divergent national standards will be withdrawn in the Member State of the European Union taking into account the transitional period indicated in the Directives.

4. Acceptance by CEN/CENELEC of this mandate will initiate the standstill period referred to article 7 of the Directive 98/34/EEC of 22 June 1998 (OJ no. L204 of 21 June 1998).

5. If, during the drafting of the standards, the structure of this programme would need to be modified, CEN/CENELEC will have to inform the Commission who will then inform the Committee for Standards and Technical Regulations. This new or modified work will normally be included in the present mandate.

6. The Commission reserves the right to specifying more precisely, if necessary, the terms of the mandate.

The work following this mandate may be updated by common agreement if that proves to be necessary during the course of the work.