



EUROPEAN COMMISSION
ENTERPRISE DIRECTORATE-GENERAL

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

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M 333 - EN

Standardization mandate to CEN concerning flammability of mattresses and bed bases for medical purposes

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.
- M/322 on “Alignment of Harmonized standards for the R&TTE Directive with those of the Medical Devices and Medical Implant Directives”.
- Mandate covering the proposed amendment to clarify matters of electrical safety in the application of EN1970 “Beds for the disabled”.

The current mandate, is a specific mandate in the application of the Council Directive 93/42/EEC on Medical Devices, dealing with flammability of mattresses and bed bases for medical purposes.

I BACKGROUND

At present no harmonised standards exist for mattresses and bed bases, which are intended for medical purposes. These mattresses and bed bases can be medical devices even when used in domestic environment. The manufacturers have adopted different solutions to meet the essential requirements and this situation has led to levels of safety considered inappropriate for such devices when used in domestic environment. This is particularly the case when Member States have provisions regarding flammability of domestic furniture, allowed under Community law, that are more stringent than standards agreed at the European level.

II MOTIVATION AND NEEDS

This present mandate is a specific mandate to cover identified needs for resistance to ignition in order to ensure the appropriate level of safety of mattresses and bed bases for medical purposes used in hospitals and in domestic environment.

In order to ensure compliance with the relevant essential requirements of the medical devices directive 93/42/EEC it would be appropriate for CEN to prepare a standard to indicate specific requirements for resistance to ignition of all mattresses and bed bases placed on the community market as medical devices or accessories to medical devices.

III STANDARDIZATION MANDATE

CEN is requested to prepare, as soon as possible, a standard to cover matters of flammability for mattresses and bed bases intended for medical purposes. This must ensure that mattress safety is specified and is presented at a level at least equal to existing European standards for domestic furniture as well as standards within the Member States. The consequences for the

environment and public health should be considered in order to minimise any negative impact. State of the art knowledge about flame retardants and possible alternative chemicals and materials with less hazardous effects on human health and the environment should be taken into account.

This mandate is for mattresses used for medical purposes only, used both inside and outside hospitals. The mandate does not cover other mattresses used in domestic environment.

Some examples of reference documents include the following:

- BS 7177 (UK), Resistance to ignition of mattresses, divans and bed bases,
- I.S. No. 316 of 1995 (Ireland), Industrial Research and Standards (Fire Safety of Domestic Furniture) Order, 1995,
- I.S. No. 419 of 1998 (Ireland), Fire Safety Requirements for Components of Furniture.
- EN 12182:1999, Technical Aids for disabled persons - General requirements and test methods,
- SS 876 00 10 (Sweden), Health care textiles - Hospital beds with high performance requirement on ignitability (mentally deranged patients),
- The report of the European Commission research programme CBUF “Fire Safety of Upholstered Furniture”, edited by Björn Sundström, SP 1995,
- UNE 53231:2000 (Spain): Plásticos. Núcleo de espuma de poliuretano (PUR) paracolchones. Características y métodos de ensayo,
- UNE 128001:1992 (Spain): Colchones y bases. Terminología y dimensiones,
- EN 597-1:1995 Furniture. Assessment of the ignitability of mattresses and upholstered bed bases. Ignition source: smouldering cigarette,
- EN 597-2:1995 Furniture. Assessment of the ignitability of mattresses and upholstered bed bases. Ignition source: match flame equivalent,
- EN 1725:1998 Domestic furniture. Beds and mattresses. Safety requirements and test methods,

- EN 60601-2-35:1997 Medical electrical equipment - Part 2: Particular requirements for the safety of blankets, pads and mattresses, intended for heating in medical use.
- Arrêté du 23 Mai 1989 (France): portant approbation de dispositions complétant le règlement de sécurité contre les risques d'incendie et de panique dans les établissements recevant du public; Article U 23 "Revêtements, gros mobilier, cloisons, matelas".

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.
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 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 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.