EUROPEAN COMMISSION
ENTERPRISE DIRECTORATE-GENERAL

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

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M/342 EN

Standardization mandate to CEN/CENELEC concerning the development of European standards relating to medical devices

(Subject: hyperbaric chambers 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 hyperbaric chambers when used for medical purposes.

I BACKGROUND

Meetings of BT Task Force 127 have discussed the suggested need to produce a European standard to cover "hyperbaric chambers for medical purposes". This work

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should take into account standardisation activities on this subject at a national and international level and particularly the standard DIN 12356-2.

The existing standardisation mandates in the medical devices field have not included the need for work on this subject, although it has been discussed a number of times when developing general mandates.

The term “Hyperbaric chamber” covers a range of devices intended for medical and/or other purposes.

II MOTIVATION AND NEEDS

Basic features for safe construction of hyperbaric chambers are covered by the Directive 97/23/EC “on the approximation of the laws of the Member States concerning pressure equipment”.

It is, however, necessary to establish specific characteristics of the environment inside the chamber when used for medical purposes, such that interface requirements with other medical devices used within the hyperbaric chamber can be indicated.

III STANDARDIZATION MANDATE

CEN and CENELEC are requested to examine and deal with the specific needs and requirements for hyperbaric chambers on medical purposes, and to prepare and adopt an appropriate standard accordingly. At least the following elements should be taken into account:

- Different features of size of the chamber which may influence the intended use.
- Different intended environment in terms of gases used and pressure ranges experienced within the chamber.
- Sources of energy and range of energy which may be available within the chamber so that appropriate safety connectors and other interfaces can be indicated.
- The need to provide sufficient information and warnings by means of labelling and other indicators.

IV EXECUTION OF THE MANDATE

1. Once CEN/CENELEC has accepted the mandate, a target date for a draft 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 EN harmonized standard will be transposed into national standards. Divergent national standards will be withdrawn in the Member States of the European Union.
4. Acceptance by CEN/CENELEC of this mandate will initiate the standstill period referred to article 7 of the Directive 98/34/EC 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.