



**Brussels, 13 June, 2002**

**M321/EN**

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

**(Subject: sub-categories for medical devices)**

**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.

This present mandate is a specific mandate to cover particular requirements for grouping medical devices under a number of collective terms or “sub-categories” for specific purposes in the application of the Council Directives: 93/42/EEC Directive on Medical Devices, 90/385/EEC Directive on Active Implantable Medical Devices and 98/79/EC Directive on In-Vitro Diagnostic Medical Devices.

## **I BACKGROUND**

It is recognized that the identified need for generic descriptors for medical devices has been satisfied by the development and adoption of the Medical Devices Nomenclature as published in CR 14230.

This present standardization mandate to CEN & CENELEC identifies the need for further work to facilitate the exchange of information as foreseen in the above Medical Devices Directives, which is not covered by the published medical devices nomenclature.

It has been emphasised that any future work in developing standards addressing specific requirements for the published medical devices nomenclature, is urgent.

## **II EXPLANATION OF THE OUTLINE OF THE FUNCTION OF THE PUBLISHED MEDICAL DEVICES NOMENCLATURE**

Work is now complete on the Medical Device Nomenclature for the purposes of identifying individual device groupings in a generic way. This nomenclature was developed in conjunction with ISO under the Vienna agreement and has received strong support from the Global Harmonisation Task Force on Medical Devices.

The Nomenclature provides the generic descriptors for medical devices and this has been published as CEN Report - CR 14230 (which is identical to International Standards Specification-ISO.TS 20225).

The publication date for both CEN and ISO reports was 1<sup>st</sup> November 2001.

The nomenclature was developed utilizing the structure presented in EN/ISO 15225 - "Nomenclature - Specification for a nomenclature system for medical devices for the purposes of regulatory data exchange" as developed under the Vienna agreement.

Terms established by the nomenclature may be used for the following:-

- ❑ collection and storage of information by regulatory authorities to identify devices placed on the market as foreseen in the relevant Medical Devices Directive
- ❑ to facilitate investigation following an incident involving a particular generic type of medical device
- ❑ when there is a need to exchange information between regulatory authorities (and other parties).
- ❑ identification of devices which are subject to a specific approval procedure prior to the issue of a certificate of compliance by a notified body.
- ❑ identify devices for purposes of stock control and purchasing.

## **III SPECIFIC NEEDS AS MOTIVATION FOR THIS PRESENT MANDATE**

It is perceived, that for certain purposes in the application of Medical Devices Directives there is an urgent need for the development of a list of **collective terms** based on the identified principles to be used, for example, as follows:

- ❑ *to illustrate the scope of certificates issued by Notified Bodies when assessing which groups, families, types of medical devices are covered within a manufacturers quality system,*
- ❑ *to be used to identify the range of skills and general technological abilities for which a Notified body has been approved, and is so appointed by the relevant Competent Authority and*
- ❑ for the exchanges of information between Competent Authorities when general information on individual manufacturers capabilities is notified for inclusion in the European Database for Medical Devices (EUDAMED).

#### **IV STANDARDIZATION MANDATE**

Having identified the needs the Commission assigns to CEN/CENELEC the task of establishing a standard (or other relevant document) to identify and establish a number of suitable collective terms. These terms to be named “sub-categories” are to be appropriate for providing general groupings to meet, in particular, the identified requirements.

The CEN standard should identify a number of principles to be used in grouping together device nomenclature terms within the proposed “sub-categories”.

These principles may include terms created on the basis of:

- ❑ Devices covered by the application of Common Technology.
- ❑ Devices manufactured for the application of similar Medical Procedures.
- ❑ Devices manufactured using similar manufacturing procedures, and with common technical features.
- ❑ Devices manufactured using common materials requiring special skills.
- ❑ Devices developed to meet specific risk-associated considerations.
- ❑ Devices requiring other family-related knowledge or skills.
- ❑ Any other identified principles of grouping.

It is anticipated that this work should result in a list of sub-categories, which would preferably not exceed 300 in number.

#### **V EXECUTION OF THE MANDATE**

1. An indication of a provisional title for the identified work presented in a systematic manner, including a target date for a draft standard 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 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.