



EUROPEAN COMMISSION  
DIRECTORATE-GENERAL ENTREPRISES

Conformity and standardisation, new approach industries under new approach  
**Pressure vessels, medical equipment and metrology**

Brussels, 9 September 1999

**M/295 - EN**

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

**I. BACKGROUND AND MOTIVATION**

This standardization mandate relates to the Council Directives 90/385/EEC and 93/42/EEC on Medical devices.

There are five standardization mandates already authorized in the field of medical devices as follows:

- 1. Mandate: BC/CEN/CENELEC/09/89**
- 2. Mandate: BC/CENELEC/02/89**
- 3. Mandate: BC/CEN/03/91**
- 4. Mandate: BC/CEN/03/023/93-08**
- 5. Mandate: BC/CEN/CENELEC/029/96**

The present standardization mandate to CEN and CENELEC is formulated to complement the earlier requests in the context of the directives on medical devices.

The experience gained during the first years during which directives 90/385 and 93/42 have been in application, has demonstrated the need for some additional standardization items. These additional items shall be performed following the principles laid down in the previous mandates.

Furthermore, in the course of this work relevant international standards (ISO and IEC, amongst others), monographies of the European Pharmacopoeia and other international documents should be identified and, where appropriate, be taken into account.

## II. STANDARDIZATION MANDATE

Having identified the needs and also taking into account the programme of work of CEN and CENELEC, the Commission assigns to CEN/CENELEC the task of establishing EN standards in the following areas:

### A. Level 1 Standards

#### 1. **Clinical investigations**

The European standard EN 540 defines general requirements for the preparation and the conduct of clinical investigations on the human being, in particular for the purpose of getting data for the clinical evaluation of medical devices. That standard is in support of annex VII of directive 90/385 and of annex X of directive 93/42.

**CEN is requested to prepare a standard which include requirements for clinical investigation plans (protocols).**

That standard will constitute an important and useful reference for manufacturers and designers of medical devices when preparing clinical investigations, as well as for Notified Bodies involved in the examination of the design or in the CE type examination of the products.

#### 2. **Risk management**

The European standard EN 1441 “Medical devices – Risk analysis” specifies a methodology for the identification of hazards and the estimation of the associated risks.

However, the process of risk management includes other aspects and other steps, in particular the decision making process which leads to accept or to refuse a risk by the evaluation of the risk/benefit ratio.

The availability of standards covering the entire risk management process would provide a greater consistency and a better harmonization of practices as far as the activities of designers and other persons involved in conformity assessment are concerned. Then, it would be easier to reduce the differences between the evaluations performed by the Notified Bodies and to avoid national deviations; it would be particularly relevant for innovative devices or when new hazards are identified.

**CEN and CENELEC are requested to prepare a standard to supersede EN 1441, covering its existing scope and extending that scope to include:**

- **at the stage of the evaluation of a risk, the decision making process relating to the acceptability of that risk and;**
- **at the stage of the reduction of a risk, the decision making process including implementation and monitoring.**

The recent experience has demonstrated that, among the factors to take into account in this area, a special attention should be given to the risks resulting from reasonable, non-intentional, misuse. Special attention should also be given to the risks associated with long term effects of implanted devices.

### **3. Traceability of medical devices to patient**

**CEN and CENELEC are requested to propose appropriate work items in this area the importance of which is increasing with respect to Public Health.**

In some cases, the rapid identification of a patient who is treated with a particular device, is an important condition for the safety of that patient. In particular, for implantable devices, it may be an issue of vital safety resulting in the application of emergency measures. Means for identifying the patients generally rely on individual patient cards and/or on procedures of registration by hospitals, with, in some cases, the co-operation of patients associations. The standardization of registration procedures and/or of the records, would increase the efficacy of those identification systems and would facilitate the compilation of technical and clinical data for the improvement of common knowledge.

## **B. Level 2 and level 3 standards**

1. Standards relating to medical devices which, in some cases, were subject of monographs or draft monographs of the European Pharmacopoeia.
  - Containers for blood, blood derivatives and infusion solutions;
  - Infusion, perfusion equipment;
  - Syringes for medical purposes;
  - Absorbent pads (cotton, etc.) for primary wound compression and absorption;
  - Wound dressings for primary wound control (e.g. control of environment, compression, absorption purposes)
  - Adhesive dressings
  
2. Respiratory and anaesthetic equipment: high pressure flexible hose assemblies for use with medical gases.

3. Operation textiles: performance requirements of coverings for invasive procedures.
4. Connections in assemblies of devices: CEN and/or CENELEC are expected to prepare a report to identify potential safety problems with these devices, e.g. Luer fittings, and to make proposals for future actions/solutions.
5. Labelling: Development of a horizontal standard on labelling for medical devices, which contain dangerous substances and which are excluded from the scope of the Directive 76/769/EEC. The concerned devices are those which are invasive, intended to be used in direct contact with patients and may present hazards to patients, users or, where applicable, other persons.
6. Hospital beds: It is suggested that all beds for medical purposes (electrical and non-electrical) should be mandated, should be covered within the scope of a generic standard to be developed and should encompass the two existing standards: beds for the disabled persons and electrically operated hospital beds.

### **III. EXECUTION OF THE MANDATE**

1. A list of provisional titles for the identified work programme presented in a systematic manner, including target dates for draft standards and for the final adoption, will be provided by CEN and CENELEC 9 months after adoption of the mandate.
2. The work will be carried out in close consultation with the Commission, including the allocation of priorities so as to achieve the completion of the work and the adoption of harmonized standards as soon as possible, taking into account the fact that the concerned directives are already applied.
3. Within 6 months after their adoption the EN harmonized standards will be transposed into national standards. Divergent national standards will be withdrawn in the Member States of the European Union taking into account the transitional period indicated in the Directive.
4. Acceptance by CEN and CENELEC of this mandate will initiate the standstill period referred to in 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 and 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 present mandates may be modified by common agreement if that proves to be necessary during the course of the work.