

Appendix 1

DRAFT STANDARDIZATION MANDATE FOR CEN/CENELEC
CONCERNING THE DEVELOPMENT OF EUROPEAN STANDARDS
RELATING TO MEDICAL DEVICES
(M/023)

I. BACKGROUND AND MOTIVATION

This standardization mandate relates to the Council Directive 93/42/EEC concerning Medical Devices.

There are three standardization mandates already authorized in the field of Medical Devices as follows :

1. *Mandate : BC/CEN/CENELEC/09/89*

Standardization mandate jointly to CEN and CENELEC concerning the preparation of European standards relating to horizontal aspects in the field of medical devices (These standards relate to both the Active Implantable Medical Devices Directive and the Medical Devices Directive)

2. *Mandate : BC/CENELEC/02/89*

Standardization mandate to CENELEC concerning the preparation of European standards relating to active implantable medical devices with reference to Council Directive 90/385/EEC of June 1990 . This mandate covered the requirement for harmonised standards covering particular (vertical) matters within the scope of this Directive.

3. *Mandate : BC/CEN/03/91*

Standardization mandate to CEN concerning the preparation of particular European standards relating to condoms. These are medical devices and fall within the scope of the Directive on Medical Devices.

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The preparation of level 3 standards are considered appropriate and necessary in the case of specific products where the level 1 or level 2 standards do not adequately address the relevant essential requirements in order to ensure an appropriate level of protection of health and safety.

Wherever relevant, these standards should address the methodology to be used to achieve the legal requirements rather than the specification of particular constructional solutions which may restrict technological evolution.

The preparation of standards provides a key element to assist in the effective operation of the Directive. This prioritized programme is mandated by the Commission to complement the Community's legislative work. It refers to mutually compatible programmes of work being prepared by CEN and CENELEC and it is necessary that these standards together with those covered by earlier mandates are developed to form part of a comprehensive and consistent set of standards. It is essential that there should be continual close coordination between CEN and CENELEC in the fulfilment of this mandate.

The work programme is extensive by necessity to cover each particular identified sector within the broad scope of the Medical Devices Directive and for which it is considered appropriate that CEN/CENELEC should prepare standards in relation to the Medical Devices Directive.

The existence of such standards will eliminate potential difficulties which otherwise may be experienced by industry in certain sectors when asked to provide justification for claims relating to compliance with the essential requirements of the directive.

It is thus important that appropriate European standards, providing a high level of protection of patients, users and other persons, should be available wherever possible before the implementation date for the directive.

In the course of this work relevant international standards and other international documents should be identified and, where appropriate, these should be adopted, after incorporating amendments as necessary, to meet the listed standardization requirements. In particular, it is recognized that the scope of this standardization mandate includes many items, especially in the field of electrical, electronic, and electro-mechanical devices which are similar in detail to those within a programme of work being undertaken or already completed at International Standardization level by ISO/IEC, and, in accordance with recognised procedures, such work where applicable should be used, with appropriate amendments, to meet the requirements of the relevant parts of this mandate.

II.2 LIST B : PRODUCT FAMILY HEADINGS*Level 2 (semi-horizontal) or level 3 (vertical) standards*

- (f) **Medical devices used in dentistry**
- General devices
 - Materials - form - surgical - dressing
 - Powered and non-powered instruments
 - Equipment - installation
 - Dental implants
- (g) **Ophthalmic optics**
- spectacle lenses
 - spectacle frames
 - contact lenses
 - contact lenses - care products
 - low vision aids
 - ophthalmic instruments
 - intraocular lenses
 - ophthalmic implants
- (h) **Surgical implants**
- General requirements
 - Neurosurgical implants
 - Cardiac and vascular implants
 - Joint replacement implants and tools
 - Osteosynthesis implants and tools
 - Breast implants
- (i) **Rescue - Transport systems and equipment**
- emergency treatment vehicle equipment
 - ambulances - device related aspects and interfaces
 - patient handling equipment
- (j) **Anaesthetic and respiratory equipment**
- Laryngoscopes
 - Conical connectors.
 - Tracheostomy tubes including paediatric
 - Humidifiers for anaesthetic and respiratory use
 - Oxygen monitors
 - Tracheal tubes and connectors
 - Anaesthetic reservoir bags
 - Oxygen concentrators
 - Manually operated resuscitators
 - Anaesthesiology - vocabulary
 - Breathing tubes
 - Capnometers
 - Pulse oximeters
 - Anaesthetic workstations
 - Pressure regulators; flow-metering devices

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- (n) **Female protective devices (devices for contraceptive use and/or to provide protection against the spread of sexually transmitted diseases)**
- **General requirements - including testing of materials, product testing, labelling, information for use, packaging**
- (o) **Laser systems for medical application**
- **Laser resistance - tracheal tubes**
 - **Surfaces for surgical instruments**
 - **Surgical drapes for use with lasers**

II.3 LIST C - PRODUCTS WITH SPECIFIC ELECTRICAL/ELECTRONIC FEATURES

List C1 -Generic safety of medical electrical equipment

Level 2 standards

- medical electrical systems - general requirements
- combination of medical electrical equipment into systems
- electromagnetic compatibility
- device-related radiation protection
- Programmable Electronic Systems - general requirements
- flammability and fire prevention aspects
- insulation protective codes
- symbols (specific to electrical features)

List C2 - Particular-equipment safety aspects

Level 2 or level 3 standards

- high frequency surgery
- short wave therapy
- ultrasound diagnostic
- ultrasonic therapy
- microwave therapy
- electroconvulsive therapy
- equipment for brachytherapy
- defibrillators/monitors
- endoscopes
- electro-optical equipment
- baby incubators
- transport incubators
- infant radiant warmers
- medical blankets (temperature controlled)
- laser devices
- equipment for magnetic resonance and imaging
- electrocardiographs
- ECG monitors
- electroencephalographs
- electromyographs and evoked response systems

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III. EXECUTION OF THE MANDATE

1. A list of provisional titles for the identified work programme prescribed in a systematic manner will be provided by CEN/CENELEC before end December 1993, including target dates for draft standards and for final adoption.
2. The work will be carried out in close consultation with EFTA, including the allocation of priorities so as to achieve the completion of the work and the adoption of harmonized standards in :
 - List A a) to d) by 1 January 1995;
 - List A item e) by 1 July 1995
 - List B by 1 July 1995;
 - List C1 by 1 July 1996;
 - List C2 by 1 July 1996
 - List D1 by 1 July 1998;
 - List D2 by 1 July 1996
3. Within six months of their adoption, the harmonized standards (EN) will be transposed into national standards and divergent national standards will be withdrawn in the EFTA countries.
4. EFTA reserves the possibility of specifying more precisely, if necessary, the terms of the mandate. The present mandate may be modified by common agreement if that proves to be necessary during the course of the work.

Standstill

5. The action of the EFTA Council decision of 24 October 1984 shall apply, if applicable, upon acceptance by CEN/CENELEC.

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