

## UNOFFICIAL PUBLICATION

No. 1506<sup>1</sup>

### Medical Devices Decree

Issued in Helsinki on 29 December 1994

-----

In response to a submission by the Minister of Social Affairs and Health, the following is enacted by virtue of §§ 2, 28 and 29 of the Medical Devices Act (1505/94) issued on 29 December 1994:

#### Chapter 1

#### General provisions

##### § 1

1) *Accessory* means any instrument, apparatus, appliance, material or other article, regardless of whether it is a medical device or not, intended specifically by its manufacturer to be used with any particular medical device to enable it to be used as intended by the manufacturer.

2) *Custom-made device* means any device made in accordance with a written prescription from a medical expert for any particular patient. The prescription must contain detailed instructions, for which the expert will be responsible, for the design of the device. Mass-produced devices needing to be adapted to meet specific requirements of a medical practitioner or other professional user are not regarded as custom-made devices.

3) *Device intended for clinical investigation* means any medical device intended to allow determination and assessment of the characteristics and performance of the device and undesirable side effects in an appropriate clinical environment.

4) *Device intended for performance evaluation* means any *in vitro* diagnostic medical device intended by the manufacturer to be subject to one or more performance evaluation studies in laboratories for medical analyses or in other appropriate environments outside his own premises. (426/2000)

5) *Device intended for self-testing* means any *in vitro* diagnostic device intended by the manufacturer to be used by other than health care professionals in a home environment. (426/2000)

6) *Manufacture of devices by health institutions* means any device manufactured and used by a health institution referred to in subparagraph 4 of § 2 of the Act on the Status and Rights of Patients. (426/2000)

## § 2

The Medical Devices Act is not applicable to

1) *abrogated* (426/2000)

2) human blood, human blood products, human plasma or blood cells of human origin or to devices incorporating at the time of placing on the market such blood products, plasma or cells,

3) *abrogated* (426/2000) or

4) transplants, tissues or cells of animal origin; however, the Act shall apply when a device is manufactured utilizing animal tissue which is rendered non-viable or non-viable products derived from animal tissue.

## § 3

Devices intended for administration of medicinal products are covered by the Medical Devices Act.

If a device intended for administration of a medicinal product is placed on the market in such a way that the device and medicinal product form one integral product intended solely for use in a given situation and not re-usable, that product is covered by the Medicines Act (395/87) but the

---

<sup>1</sup> Amendment on Council of State Decree 426/2000

safety and performance characteristics of the device are covered by the Medical Devices Act.

If a substance that may have an action ancillary to that of the device on the human body is integrally incorporated in the device, the device must be evaluated and authorized in accordance with the Medical Devices Act regardless of whether or not the substance in question is regarded as a medicinal product as referred to in the Medicines Act.

#### § 4

Accessories are covered by the Medical Devices Act and the provisions pursuant to it.

The Medical Devices Act covers personal protective equipment where the manufacturer intends the equipment to be used principally for the purpose stated under § 3 point 1 of the Medical Devices Act.

The Medical Devices Act is applicable to medical devices and accessories intended for *in vitro* diagnostics so that also *in vitro* diagnostic devices containing human tissue or cells or their derivatives shall be governed by the provisions of the Act. (426/2000)

#### § 4a

(426/2000) The Medical Devices Act is applicable to the manufacture of devices by health institutions. However, a notification of manufacture referred to in the Act need not be made to the product register kept by the National Agency for Medicines.

The provisions concerning the manufacture of devices by health institutions are also applicable to cases where a health institution alters the intended use stated by the manufacturer of a device or gives a device an intended use as a medical device.

Detailed provisions on ensuring conformity to requirements and the related procedures concerning medical devices manufactured by health institutions are set out in the Decree of the Ministry of Social Affairs and Health.

#### § 4b

(426/2000) The Medical Devices Act is applicable to medical devices containing non-

viable human tissue or cells or their derivatives.

Detailed provisions on the requirements and the procedures for ensuring conformity to requirements of the devices referred to in paragraph 1 are set out in the Decree of the Ministry of Social Affairs and Health.

## Chapter 2

### **Essential requirements**

#### § 5

Medical devices must be designed and manufactured in such a way that when used under the conditions and for the purposes intended they meet the essential requirements relating to health and safety. Any risks associated with their use must be acceptable in relation to benefits to the patient. Information accompanying the device must allow its safe use.

#### § 6

Any health risks associated with use of the device must be investigated during its design and manufacture. Users must be informed about any risks that cannot be eliminated.

Any undesirable or side effects of a medical device must be acceptable in relation to the intended performance of the device.

#### § 7

When safety dictates, a manufacturer must provide necessary information about use, storage and transport of a medical device.

#### § 8

A medical device will meet essential requirements if it has been designed, manufactured and fitted with appropriate equipment in accordance with relevant national standards and such standards have been adopted pursuant to harmonized standards the references of which have been published in the Official Journal of the European Communities.

Harmonized standards also include those requirements in the European Pharmacopoeia the references of which have been published in the Official Journal of the European Communities

and which relate in particular to surgical sutures and interactions between medicinal products and materials used in devices containing such medicinal products.

Essential requirements may also be met in ways other than those referred to in Subsections 1 and 2.

#### § 9

The manufacturer must operate an up-to-date systematic procedure by which information obtained about any medical device may be assessed and investigated.

#### § 10

Adequate care must be taken and cleanliness observed during storage, transport or other handling of a medical device.

The National Agency for Medicines may give more detailed instructions on the quality assurance procedures to be followed in the cleaning, sterilisation, calibration, maintenance and other measures taken to ensure the reliability of medical devices. (426/2000)

#### § 11

The manufacturer must keep information relating to conformity and other information necessary for surveillance for a period of at least five years after termination of manufacture of a medical device or after a medical device intended for clinical investigation or a custom-made device has been manufactured.

### Chapter 3

#### **Notified body**

#### § 12

The notified body and staff involved in assessment and verification must have competence, experience and administrative skills requisite to the field of medical devices. The notified body must be able to carry out all tasks assigned to such bodies as regards assessment of conformity of

products and must have the qualifications prescribed in the relevant European Community Act concerning testing, inspection and verification procedures.

In approving a body as a notified body the Ministry of Social Affairs and Health may impose conditions necessary to ensure its appropriate function.

If the body no longer meets criteria for its designation as a notified body or does not meet requirements established for its operation notification must be withdrawn.

### § 13

A notified body may not, without good reason, refuse to conclude an agreement with any manufacturer operating in the European Economic Area or with his authorized representative established in the European Economic Area if the agreement relates to tasks which the body has been designated to undertake.

The notified body and its staff must be in a position to conduct assessments impartially.

The notified body must not accept any assessment task if there is reason to believe that it will not be able to carry out the task impartially.

### § 14

The notified body must carry civil liability insurance adequate in relation to the scope and nature of its function unless liability for any damages caused by it is assumed by the State.

### § 15

The notified body may require, with appropriate justification, a manufacturer to provide any information necessary for establishing and maintaining the attestation of conformity in view of the chosen procedure.

The notified body and the manufacturer or his authorized representative established in the European Economic Area shall lay down, by common accord, the time limits for completion of assessment and verification operations in relation to full quality assurance and product quality

assurance.

During assessment of conformity the notified body shall, where appropriate, take account of the results of any assessment and verification operations carried out during manufacture.

#### § 16

Records and correspondence relating to conformity assessment shall be in Finnish or Swedish. The notified body may also accept records and correspondence in any other language of the European Economic Area.

### Chapter 4

#### **Labelling**

#### § 17

When a medical device is placed on the market it must bear the CE marking of conformity except in the cases referred to in § 19. By applying the CE marking the manufacturer asserts that a device meets the essential requirements.

The CE marking must be applied visibly, legibly and indelibly to a device or its sterile pack, where possible and appropriate, and on the instructions for use. Where necessary, the CE marking must also appear on the sales packaging.

The CE marking shall be accompanied by the identification number of the notified body responsible for implementation of the conformity assessment procedure.

#### § 18

Application of marks resembling the CE marking to a medical device is prohibited. Any other mark may be applied to a device, packaging or instruction leaflet accompanying a device provided that the visibility and legibility of the CE marking is not thereby impaired.

Information accompanying the device must be in Finnish, Swedish or English, unless the

information takes the form of generally known direction or warning symbols. Information intended for users or patients to ensure the safe use of the device must be in Finnish and Swedish.

The instructions for use and labelling of medical devices intended for self-care must be in Finnish and Swedish. (426/2000)

#### § 19

(426/2000) CE-marking may not be affixed to custom-made devices and devices intended for clinical research and performance evaluation.

Devices manufactured by a health institution or the documentation accompanying them must indicate the manufacturing unit and the intended use of the device.

### Chapter 5

#### **Marketing**

#### § 20

Advertising and other means of promotion of sales of medical devices must not be inappropriate or involve exaggerated or erroneous representations of the composition or efficacy of the devices.

### Chapter 6

#### **Miscellaneous provisions**

#### § 21

In addition to what is prescribed in § 14 and § 30 of the Medical Devices Act, the National Agency for Medicines shall

- 1) undertake tasks assigned to competent authorities by Acts of the European Community relating to medical devices,
- 2) monitor the functioning of notified bodies as referred to in this Decree,
- 3) perform inspections required by product control in the manufacturer's premises and

monitor and assess the safety and quality of use of medical devices, (426/2000)

- 4) promote product safety in the field by disseminating relevant information,
- 5) keep registers and maintain expert and information networks in the field, and
- 6) carry out any other tasks prescribed for or assigned to it.

## § 22

The National Agency for Medicines shall without delay process notifications made by manufacturers and professional users concerning adverse incidents caused by medical devices. Following any notification, a report must be requested from the manufacturer of the device or his authorized representative established in the European Economic Area if there is good reason to believe that the adverse incident has resulted from any malfunction or change in the characteristics or performance of the device in question.

The National Agency for Medicines shall determine measures to be taken on the basis of the notification, as far as practicable together with the manufacturer or his authorized representative referred to in Subsection 1.

## § 23

The Ministry of Social Affairs and Health shall issue specific provisions relating to classification, essential requirements and conformity assessment procedures in relation to medical devices as required in the relevant Acts of the European Community.

## § 24<sup>2</sup>

---

<sup>2</sup> Decree 426/2000 came into force on 1 June 2000. However, the provisions of paragraph 2 of § 31 of the Medical Devices Act shall be applied to *in vitro* diagnostic medical devices if the devices have not been placed on the market or put into service in accordance with Directive 98/79/EC on *in vitro* diagnostic medical devices until 7 December 2003. An *in vitro* diagnostic medical device that meets the requirements of paragraph 2 of § 31 of the Medical Devices Act may be put into service until 7 December 2005.

The provisions concerning manufacture by health institutions shall be applied to medical devices manufactured or put into service on or after 1 January 2001. However, *in vitro* diagnostic medical devices manufactured and used by the same health institution may be manufactured and put into service until 1 December 2003 even if their conformity to requirements has not been ensured in accordance with § 4a of this Decree.

This Decree will come into force on 1 January 1995.

Measures necessary for implementation of this Decree may be taken before this Decree comes into force.

Where a medical device bears the CE marking affixed on the basis of an Act covering the device other than the Medical Devices Act and the Act in question or provisions pursuant to it allow the manufacturer, during a transitional period, to choose which arrangement to apply, the CE marking shall indicate that the devices only meet provisions applied by the manufacturer. In such a case, particulars of the European Community Acts as published in the Official Journal of the European Communities must be given in documents, notices or instructions accompanying such devices as required by the Acts in question.

---