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MEDICAL DEVICES ACT (1505/94)
Amended by Act 680/1999 and Act 345/2000

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Chapter 1

General provisions

§ 1

Purpose of the Act

The purpose of this Act is to maintain and promote the safety and safe use of medical devices.

§ 2

Scope

(345/2000) This Act shall apply to the planning, manufacture, packaging, marking, placing on the market, putting into service, professional use and marketing of medical devices. The Act shall be applied as appropriate to the manufacture of devices by the health care services.

Further provisions on the manufacture of devices by the health care services are given in the relevant Decree.

The Act shall be applied only to the extent provided by the Decree to products containing human or animal tissue or cells or their byproducts or other products used like or together with medical devices. Moreover, it may be provided in the Decree that the provisions of this Act shall not apply or shall only apply as appropriate to medical devices referred to in the Decree.

§ 3

Definitions

1) *Medical device* means any instrument, apparatus, appliance, material or other article whether used alone or in combination, including the software necessary for its proper function, intended by the manufacturer to be used in relation to human beings for the purpose of:

- a) diagnosis, prevention, monitoring, treatment or alleviation of disease,
- b) diagnosis, prevention, monitoring, treatment, alleviation of or compensation for an injury,
- c) investigation, replacement or modification of the anatomy or of a physiological process, or
- d) control of conception.

Functioning of a medical device as referred to in Subsection 1 may be assisted through pharmacological, immunological or metabolic means, provided that its principal intended action is not achieved by such means.

1 a) *in vitro* diagnostic medical device means any medical device which is a reagent, reagent product, calibrator, control material, test kit, instrument, apparatus, equipment or system, whether used alone or in combination, intended by the manufacturer to be used *in vitro* for the examination of specimens derived from the human body solely or principally for the purpose of providing information:

- a) concerning a physiological or pathological state;
- b) concerning a congenital abnormality;
- c) to determine the safety and compatibility in connection with blood and tissue donations; or
- d) to monitor therapeutic measures. (345/2000)

2) *Manufacturer* means the natural or legal person who places a medical device on the market

under his own name. The natural or legal person who assembles, packages, processes, fully refurbishes or labels one or more ready-made products or assigns to them their intended purpose as a medical device with a view to their being placed on the market under his own name.

3) *Professional user* means

a) a health-care unit as referred to in § 2 point 4 of the Act (785/92) concerning the position and rights of patients, a social welfare unit as referred to in § 24 of the Social Welfare Act (710/82), and a special welfare unit as referred to in § 9 of the Act (519/77) concerning the special welfare of the mentally retarded,

b) a health-care professional using a medical device in the course of his or her professional activity, or

c) another natural or legal person supplying medical devices without being a retailer or wholesaler.

4) *Intended purpose* means the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions for use, or in promotional material.

5) *Placing on the market* means the first making available in return for payment or free of charge of a medical device with a view of distribution or use in the European Community regardless of whether it is new or fully refurbished. The use of a medical device for clinical research or for performance evaluation of a medical device is not considered to be placing on the market. (345/2000)

6) *Putting into service* means the stage at which a medical device has been made available to the final user as being ready for use for the first time for its intended purpose in the European Community. (345/2000)

7) *Authorised representative* means any natural or legal person established in the European Community who, explicitly designated by the manufacturer, acts and may be addressed by authorities and bodies instead of the manufacturer with regard to the latter's obligations under this Act and the provisions and stipulations pursuant to it. (345/2000)

§ 4

Relationship with other regulations

Provisions concerning supervision of use of devices emitting radiation, radioactive substances and products relating to safe use of radiation are laid down in the Radiation Act (592/91).

Provisions concerning medicinal products are laid down in the Medicines Act (395/87).

Chapter 2

Medical devices

§ 5

Manufacturer's general obligations

The devices must be designed, manufactured, packed and labelled in such a way as to make them suitable for the functions intended by the manufacturer.

The manufacturer is responsible for the design, manufacture, packaging and labelling of a

medical device, regardless of whether these operations are carried out by the manufacturer himself or on his behalf by a third party.

§ 6

Essential requirements concerning medical devices

Medical devices must meet the requirements defined for them. They must be suitable for their intended purposes and must fulfil their intended function and performance when used for the purposes intended. Appropriate use of the device must not compromise the health or safety of a patient, user or other person.

Medical devices are placed in Class I, IIa, IIb or III, depending on the vulnerability of the body and intended use of the device.

In demonstrating conformity of a medical device with relevant requirements and in the related approval the manufacturer must apply tests and inspections carried out by a notified body as referred to in § 28 and other conformity assurance procedures.

§ 7

Adverse incident notification by manufacturer

The manufacturer must inform the National Agency for Medicines about any malfunction or deterioration in the characteristics or performance of a medical device or any inadequacy in the labelling or instructions for use which have led to or might have led to the death or serious deterioration in the state of health of a patient, user or other person.

The manufacturer must inform the National Agency for Medicines about any technical or medical reason relating to the characteristics or performance of a medical device that leads to systematic recall of the device from the market by the manufacturer.

The National Agency for Medicines keeps a register (*Adverse Incident Register*) in which notifications as referred to in Subsections 1 and 2 and in § 13 will be entered.

§ 7a

Adverse incident notification by importer

(345/2000) The importer of medical devices must notify the manufacturer of the devices of all adverse incidents that have come to his knowledge, which have been or may have been due to a malfunction or deterioration of a medical device.

§ 8

Notification of clinical investigation

If a manufacturer intends to carry out *clinical investigations* to verify the performance or to determine and assess the side effects of a medical device prior to placing the device on the market he shall make a relevant notification to the National Agency for Medicines before starting clinical investigations. The manufacturer may commence investigations after making such a notification. In the case of Class III devices, implantable devices and Class IIa or IIb long-term invasive devices the manufacturer may commence a relevant clinical investigation at the end of a period of 60 days after notification, unless the National Agency for Medicines has previously advised that the investigations are forbidden for public health reasons.

The provisions of Subsection 1 also apply where the clinical investigations are conducted to investigate a new purpose for use of a medical device regardless of whether the device has been placed on the market or put into service.

The National Agency for Medicines may, on application, authorise manufacturers to commence a relevant clinical investigation before the expiry of the period referred to in Subsection 1, if a relevant ethics committee has issued a favourable opinion on the investigation.

§ 9

Discontinuation of investigation

The National Agency for Medicines may order a clinical investigation to be discontinued if this is considered necessary for public health reasons.

Chapter 3

Placing on the market, putting into service and professional use

§ 10

Placing on the market and putting into service

(345/2000) A medical device may be placed on the market or put into service once it meets the requirements laid down in this Act and the provisions pursuant to it. The Ministry of Social Affairs and Health may decide that the identification data and details of markings and user instructions of a medical device that may cause a significant health risk must be submitted to the National Agency for Medicines.

A medical device may be put on display even though it does not meet the requirements of Paragraph 1, if it is provided with a clear marking indicating that the device cannot be placed on the market and put into service before it has been made to comply with the requirements. *in vitro* diagnostic medical devices on display may not be used for processing samples received from persons present at the display.

§ 11

Ensuring reliability of function

A professional user shall take the necessary measures to ensure that

- a) the condition of a medical device is on a level required by the law;
- b) the place of use, the components and structures affecting the safe use and devices, articles and equipment relating to the medical device do not compromise its performance or the health or safety of a patient, user or other person; and
- c) the instructions and procedures concerning the use are appropriate. (345/2000)

Medical devices may be installed, serviced and repaired only by persons with the necessary professional skills and expertise.

§ 12

General requirements concerning professional use, and quality assurance

A person using a medical device shall have adequate user training and experience. A professional user shall ensure that persons using medical devices have appropriate training and experience and that the necessary labelling and instructions for the safe use of the device are provided on or with the medical device. (345/2000)

A medical device must be used in accordance with the intended purpose stated for the device.

A professional user shall ensure that the device is placed, adjusted, maintained and serviced appropriately to ensure it remains in working order.

A professional user shall keep a list of medical devices used or hired out by him or in his possession or introduced into a patient.

§ 13

Assessment and notification of adverse incidents

Units active in social and health care shall have a systematic procedure for assessing and following up adverse incidents connected with the use of medical devices. The systematic procedure for assessing and following up adverse incidents connected with the use of medical devices applies also to the health care professionals as appropriate. (345/2000)

The professional user must inform the National Agency for Medicines about any malfunction or deterioration in the characteristics or performance of a medical device or any inadequacy in the labelling or instructions for use which have led to or might have led to the death or serious deterioration in the state of health of a patient, user or other person.

Provisions concerning the maintenance of the *Adverse Incident Register* are laid down in § 7.

Chapter 4

Direction and supervision

§ 14

Direction and supervision

General direction in relation to this Act shall be the responsibility of the Ministry of Social Affairs and Health.

Compliance with this Act and with the provisions pursuant to it shall be directed and supervised by the National Agency for Medicines.

§ 15

Product register

(345/2000) A Finnish manufacturer must send a notification to the product register stating the name and address of his company, place of business, identification data of the medical device, details of the certificates or rejections by the notified body and other information required for market control. Notification must also be made when the information referred to previously in this Section change. An authorised representative established in Finland must submit a

corresponding notification. The notification shall be sent to the National Agency for Medicines. A device containing human tissue or substances derived from human blood or blood plasma shall likewise be notified.

The National Agency for Medicines may require that a notified body submit the details of medical devices referred to in the foregoing when it has participated in their conformity assessment.

The National Agency for Medicines shall send the registration data of *in vitro* diagnostic medical devices referred to in Directive 98/79/EC on *in vitro* diagnostic medical devices to the European database, which is accessible to the competent authorities. The data collected in the database may only be used purposes of control by the authorities.

§ 16

Right to obtain information

The National Agency for Medicines has a right to obtain the information necessary for supervision from government and municipal authorities and businessmen and persons to whom the provisions in this Act or provisions pursuant to this Act apply.

The right to obtain information also applies to information necessary for appropriate supervision and concerning the private business or professional activities or the financial situation of a private person that would otherwise be confidential.

§ 17

Powers relating to market control

The National Agency for Medicines has a right to conduct inspections and investigations required by post-marketing surveillance and to this end to have access to places in which activities as referred to in this Act are pursued, to carry out inspections and take other measures necessary for supervision.

The National Agency for Medicines has a right to take samples of medical devices and to obtain the required number of medical devices as test items. The sample and test items shall be reimbursed at current price if the possessor requires this. However, samples and test items shall not be reimbursed if the investigation reveals that the device is in contravention of this Act or the provisions pursuant to it.

The police must provide such assistance as may be necessary for performance of duties as stipulated in this Section.

18 §

Confidentiality

(680/1999) Without prejudice to what is stipulated about confidentiality in Act 621/1999 on the publicity of the actions of the authorities, anyone who in the performance of a task relating to the supervision of compliance with this Act or the provisions pursuant to it, has obtained information about the financial status, trade or professional secrets of a private person or corporation, or about the state of health or personal situation of any private person, may disclose such information to

- 1) government authorities for the performance of the tasks stipulated in this Act;
- 2) prosecuting, police or customs authorities for investigation of a criminal offence;

- 3) authorities or a notified body for the purpose of exchanging information;
- 4) foreign official bodies and notified bodies supervising medical

Chapter 5

Prohibitions and restrictions

§ 19

Restrictions concerning manufacture and sales

(345/2000) If a medical device contravenes this Act or the provisions pursuant to it, or if CE marking has been wrongly affixed to it, the National Agency for Medicines may

- 1) oblige the manufacturer to take measures necessary to make it comply with this Act and the provisions pursuant to it; or
- 2) forbid the manufacture, sale or release in connection with other business activity of the device.

If documents allowing for the assessment of conformity to requirements have not been produced for a medical device that has been placed on the market or put into service, or if the documents submitted by the manufacturer are deficient or faulty, the National Agency for Medicines may order the manufacturer to produce the missing documents or remedying the deficiencies or faults. If, in spite of the order by the National Agency for Medicines, the deficiencies or faults are not set right, the National Agency for Medicines may prohibit the manufacture, sale or release in connection with other business activity of the medical device.

The aforesaid ruling shall apply also when CE marking intended for medical devices has been affixed to products other than medical devices.

In advance of a final decision, the National Agency for Medicines may issue an interim decision when there are special grounds for it.

§ 20

Prohibition of or restrictions on professional use

If considered necessary for public health reasons, the National Agency for Medicines may forbid professional use of a medical device or impose restrictions on it.

§ 21

Obligations regarding medical devices already in use

When the National Agency for Medicines has issued a decision relating to prohibition of a medical device under § 19, it may order the manufacturer to take measures relating to medical devices already in use, to prevent danger arising from use of the devices.

The order referred to in Subsection 1 may oblige the manufacturer to

- 1) modify the medical device in question in such a way as to eliminate any health risk resulting from malfunction or defect in its characteristics or performance or from untruthful, misleading or inadequate information given about the device (*modification*), or

2) withdraw from the market medical devices that could for technical or medical reasons compromise the health of any patient, user or other person (*withdrawal from the market*). The National Agency for Medicines may also issue an order as referred to in Subsections 1 and 2 if a decision as referred to in § 19 cannot be taken because the medical devices in question are no longer in the possession of the manufacturer or the manufacturer or his representative cannot be reached and there are significant reasons for issuing such an order.

§ 22

Notification obligation

The National Agency for Medicines may oblige a manufacturer to issue in an appropriate way notification of any prohibition or order, any health risk associated with a medical device or its use and any procedures to eliminate any health risk.

§ 23

Conditional imposition of a fine

Any obligation to provide information as stipulated by the National Agency for Medicines under § 16, any decision concerning a particular manufacturer made by the National Agency for Medicines under § 19 and § 21 and any notification obligation stipulated by the Agency under § 22 may be supplemented by conditional imposition of a fine as stipulated in the Act (1113/90) concerning conditional imposition of a fine.

Chapter 6

Provisions relating to punishments and forfeiture

§ 24

Violation of provisions concerning product safety

Anyone who in contravention of this Act or the provisions pursuant to it

- 1) manufactures, packages, labels, sells, otherwise releases in connection with business activities or imports medical devices as referred to in Section 3,
 - 2) fails to submit a notification to the product register, a notification of clinical studies or the manufacturer's adverse incident notification, or
 - 3) violates an order or a prohibition issued by the authorities by virtue of this Act,
- shall be fined for violation of *product safety of health care*, unless a more severe punishment is prescribed elsewhere in the law.

The National Agency may decide not to report any violation that overall can clearly be considered insignificant. (345/2000)

Any person who acts in contravention of a prohibition or obligation pursuant to § 23 intensified by a conditionally imposed fine cannot be sentenced to punishment for the same act.

(§ 25) Abrogated (680/1999)

§ 26
Forfeiture

A medical device that has been placed on the market or put into service in contravention of this Act or provisions pursuant to it, the value of the device and any financial gain from the offence shall be declared forfeit to the State.

Forfeiture may be waived or limited to only part of the property and any financial gain if it would be unreasonable having regard to all of the circumstances.

An official having the right of arrest may confiscate a medical device referred to in this Act if the device is likely to be declared forfeit to the State.

Chapter 7

Appeal against and implementation of decisions

§ 27
Appeal

The court of appeal in relation to decisions taken by the National Agency for Medicines under this Act is the Supreme Administrative Court as prescribed in the Act concerning appeal in relation to administrative matters (154/50).

An order issued by the National Agency for Medicines in connection with an inspection of the manufacturer's production facilities is not applicable. Anyone dissatisfied with the order is entitled to have the order heard by the National Agency for Medicines upon request within 30 days from the end of the inspection. The order shall be accompanied by instructions on submitting a claim of rectification for the decision by the National Agency for Medicines. Measures contained in the order shall be taken despite a claim of rectification. The decision concerning the claim of rectification by the National Agency for Medicines may be appealed as stipulated in paragraph 1. (345/2000)

Decisions taken and orders given by the National Agency for Medicines under §§ 19 to 22 shall be complied with regardless of any appeal, unless the appeal authority shall decide otherwise.

No appeal against a temporary decision taken under § 19 is allowed.

Chapter 8

Miscellaneous provisions

§ 28
Notified body

Assessment of conformity of medical devices with relevant requirements as prescribed in this Act and in provisions pursuant to it shall be conducted by a body notified to the European Commission as regards the assessment procedures and product groups specified in the notification.

The Ministry of Social Affairs and Health shall decide about any notification concerning a Finnish body, or withdrawal of such a notification.

At the request of the National Agency for Medicines, the notified body shall submit to the supervisory authorities all relevant data and documents, including financial documents needed to ascertain that the body conforms to the prescribed requirements. (345/2000)

More specific provisions concerning demands on a notified body and its tasks and responsibilities are given in the relevant Decree.

§ 28 a

Notification obligation of notified body

(345/2000) The notified body shall inform other notified bodies and competent authorities of all certificates cancelled for a fixed term or entirely and, on request, of issued or rejected certificates. Moreover, the notified body shall provide relevant additional details on request.

§ 28 b

Cancellation of certificate

(345/2000) If a notified body ascertains that a manufacturer has failed to meet or no longer meets the requirements referred to in Section 10, or that a certificate should otherwise not have been granted, the notified body shall cancel the certificate for a fixed term or entirely or grant a limited certificate if the manufacturer does not remedy the deficiencies. If deficiencies are identified in a certificate that has been granted, the notified body shall inform the National Agency for Medicines immediately when the deficiency or other reason has been brought to its knowledge.

§ 29

Detailed provisions and regulations

Detailed provisions may be given in the relevant Decree as regards

- 1) essential requirements relating to medical devices, their classification and conformity assessment procedures, and
- 2) marketing.

The relevant Decree may authorise the Ministry of Social Affairs and Health to issue more specific rules concerning matters referred to in Point 1 above.

The Ministry of Social Affairs and Health may prohibit the putting into service of a medical device or a product group or impose conditions on the use or availability if necessary for the protection of health or safety or for special public health reasons. (345/2000)

§ 30

Powers of the National Agency for Medicines

The National Agency for Medicines shall

- 1) when necessary, decide whether or not a device is to be considered a medical device,
- 2) decide the product class, to which a medical device belongs if there is disagreement between a notified body and the manufacturer,
- 3) when necessary, oblige the manufacturer to present information about custom-made devices put into service in Finland,
- 4) on application, issue permission for placing on the market and putting into service an individual medical device despite the fact that no assessment of conformity has been carried out as required in this Act or in provisions pursuant to it, if the use of the device is important for the protection of public health in Finland, and
- 5) when necessary, issue technical and safety-related instructions and instructions relating to adverse-incident notification and notifications made to the product register and instructions relating to clinical investigations and information to be given about such investigations.

Chapter 9

Coming into force and transitional provisions

§ 31

Coming into force

This Act will come into force on 1 January 1995.

This Act will abrogate the Medical Devices Act (997/84) of 28 December 1984 and its subsequent amendments. However, provisions of the Act to be abrogated shall be applied to in vitro diagnostic devices in so far as provisions in this Act are not applicable.

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

§ 32

Transitional provisions

A manufacturer or importer of medical devices or other person responsible for placing medical devices on the market or putting them into service may place a medical device on the market or put it into service until 13 June 1998 even if a device does not meet the requirements laid down in this Act or in provisions pursuant to it if the device conforms to provisions effective at the time this Act came into force. However, § 7 of the Medical Devices Act as amended by the Act (791/92) of 21 August 1992 shall not be applied when placing devices on the market or putting them into service after abrogation of the Act. Provisions in Subsection 1 notwithstanding, the provisions of this Act shall apply to active implantable medical devices.

Mercury thermometers that have received EC type-approval as referred to in Directive (76/764/EEC) of 27 July 1976 on the approximation of the laws of the Member States on clinical mercury-in-glass, maximum reading thermometers may be placed on the market and put into service until 30 June 2004.

The provisions and directions issued by the Ministry of Social Affairs and Health and the National Research and Development Centre for Welfare and Health before this Act came into force shall remain in force until further notice but not after 13 June 1998.

[This Act will not impose restrictions on the sales and other release or use of medical devices as referred to in Subsection 1 that are in wholesale or retail sale or in professional use on 13 June 1998 if the devices meet the requirements in Subsection 1 above.]¹

¹ Medical devices referred to in the Decision of the Ministry of Social Affairs and Health of 29 December 1994 (66/1994) may be put into service until 30 June 2001 if the medical device conforms to the provisions and regulations in force on 31 December 1994. (Act 345/2000)