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Medical Devices Act¹

Passed 13.10.2004
RT I 2004, 75, 520
Entry into force 01.12.2004

Amended by the following acts

Passed	Published	Entry into force
09.02.2005	RT I 2005, 13, 63	01.05.2005
24.01.2007	RT I 2007, 12, 66	01.01.2008
30.09.2009	RT I 2009, 49, 331	01.01.2010 «Health Care Board» and «State Agency of Medicines» replaced with «Health Board» in this Act
22.04.2010	RT I 2010, 22, 108	01.01.2011, enters into force on the date which has been determined in the Decision of the Council of the European Union regarding the abrogation of the derogation established in respect of the Republic of Estonia on the basis provided for in Article 140 (2) of the Treaty on the Functioning of the European Union, Council Decision 2010/416/EU of 13 July 2010 (OJ L 196, 28.07.2010, p. 24 - 26).
20.05.2010	RT I 2010, 31, 158	01.10.2010
10.11.2010	RT I, 30.11.2010, 11	10.12.2010, partially 01.01.2011 and 01.03.2011
15.11.2013	RT I, 29.11.2013, 1	09.12.2013
19.02.2014	RT I, 13.03.2014, 4	01.07.2014
26.03.2014	RT I, 15.04.2014, 1	01.05.2014
19.06.2014	RT I, 29.06.2014, 109	01.07.2014, official titles of ministers replaced on the basis of subsection 107 ³ (4) of the Government of the Republic Act

Chapter 1 GENERAL PROVISIONS

§ 1. Scope of application of Act

- (1) With the aim of protecting the safety and health of persons, this Act provides the requirements for:
- 1) medical devices and accessories (hereinafter medical devices) and the manufacture thereof;
 - 2) placing on the market and putting into service of medical devices;
 - 3) providing clinical evaluation of medical devices;
 - 4) the professional users of medical devices.
 - 5) the sale of medical devices on the basis of medical device card.

[RT I, 29.11.2013, 1 – entry into force 09.12.2013]

(2) This Act does not apply to the users, manufacture, placing on the market and putting into service of the following products:

- 1) cosmetic products covered by Council Directive 76/768/EEC on the approximation of the laws of the Member States relating to cosmetic products (OJ L 262, 27.09.1976, p. 176–200);
- 2) personal protective equipment covered by Council Directive 89/686/EEC on the approximation of the laws of the Member States relating to personal protective equipment (OJ L 399, 30.12.1989, p. 18–38);
- 3) transplants of tissues or cells of human origin, and products incorporating or derived from tissues or cells of human origin;
- 4) transplants of tissues or cells of animal origin, except for products manufactured from animal tissue which is non-viable or rendered non-viable;
- 5) *in vitro* diagnostic medical devices produced and used only within the facilities related to the production activities of the relevant health care provider, however, the requirements provided in § 17 of this Act apply to such devices.

§ 2. Application of other Acts

(1) To guarantee the radiation safety of medical devices emitting ionising radiation, the provisions of the Radiation Act applicable to medical devices shall be observed upon the manufacture and use of such devices in addition to the requirements established by this Act.

(1¹) The Medicinal Products Act shall apply, with the specifications arising from the Blood Act, to products manufactured from human blood which are used in medical devices.
[RT I 2005, 13, 63 – entry into force 01.05.2005]

(2) If a medical device is placed on the market in such a way that the device and the medicinal product form a single integral product which is intended exclusively for use in the given combination and which is not reusable, the relevant medical device shall be governed by the Medicinal Products Act and the requirements of this Act, whereas the requirements of this Act shall apply as far as safety and performance related device features are concerned.

(3) Where a medical device incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in the Medicinal Products Act and which is liable to act upon the body with action ancillary to that of the device, only the requirements of this Act apply to the medical device.

(3¹) A device intended for the administration of medicinal product for the purposes of § 2 of the Medicinal Products Act shall be deemed to be a medical device and the provisions of this Act shall be applied to it.
[RT I, 30.11.2010, 11 – entry into force 10.12.2010]

(4) To ensure the safety of the medical gas pipelines supplying health care providers with medical gas, the provisions of the Pressure Equipment Safety Act applicable to medical gas pipeline systems shall be observed upon the manufacture and use of such devices in addition to the requirements established by this Act.

(5) The provisions of the Product Conformity Act shall apply to the duties of the manufacturer, authorised representative thereof, importer and distributor of medical devices, notified body, conformity attestation of medical devices and to market supervision with the specifications arising from this Act.
[RT I 2010, 31, 158 – entry into force 01.10.2010]

(6) [Repealed - RT I 2010, 31, 158 – entry into force 01.10.2010]

(7) The Administrative Procedure Act applies to administrative proceedings prescribed in this Act, taking account of the specifications provided for in this Act.

(8) [Repealed - RT I 2010, 31, 158 – entry into force 01.10.2010]

(9) A medical device, the use of which has also been regulated by Directive 2006/42/EC of the European Parliament and of the Council on machinery, and amending Directive 95/16/EC (OJ L 157, 9.06.2006, p. 24–86), shall also comply with the health protection and safety requirements established in the given Directive if these requirements are more detailed than the requirements laid down in this Act and in legislation established on the basis thereof.
[RT I, 30.11.2010, 11 – entry into force 10.12.2010]

(10) A medical device, the use of which has also been regulated by the Council Directive 89/686/EEC on the approximation of the laws of the Member States relating to personal protective equipment (OJ L 399, 30.12.1989, p. 18–38), shall also comply with the health protection and safety requirements established in the given Directive if these requirements are more detailed than the requirements laid down in this Act and in legislation established on the basis thereof.
[RT I, 30.11.2010, 11 – entry into force 10.12.2010]

§ 3. Medical device

(1) Medical device shall mean any instrument, apparatus, appliance, software, material or other product used on humans, whether used alone or in a combination, including the software determined by the manufacturer specifically for diagnostic or medical treatment purposes which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, intended by the manufacturer to be used for human beings for the purpose of:

- 1) diagnosis, prevention, monitoring, treatment or alleviation of diseases;
- 2) diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability;
- 3) investigation or modification of the anatomy or of a physiological process or replacement of a part of body;
- 4) assisting or prevention of conception.

(2) If a product complies with the requirements specified in subsection (1) of this section, the Health Board shall have the right to identify the product as a medical device.

[RT I, 30.11.2010, 11 – entry into force 10.12.2010]

§ 4. Accessory

For the purposes of this Act, an accessory shall mean a device which, whilst not being a medical device if used alone, is intended specifically by its manufacturer to be used together with a medical device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device.

[RT I, 30.11.2010, 11 – entry into force 10.12.2010]

§ 4¹. Active medical device

An active medical device is a medical device, which relies for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity.

[RT I, 30.11.2010, 11 – entry into force 10.12.2010]

§ 5. Active implantable medical device

An active implantable medical device is an active medical device which is totally or partly introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure.

[RT I, 30.11.2010, 11 – entry into force 10.12.2010]

§ 6. *In vitro*diagnostic medical device

(1) *In vitro*diagnostic medical device means a reagent, reagent product, calibrator, control material or kit, instrument, apparatus, equipment or system, whether used alone or in combination, intended by the manufacturer to be used *in vitro* for the laboratory examination of specimens, including blood and tissue donations, derived from the human body, for the purpose of providing information concerning a physiological or pathological state, or concerning a congenital abnormality or examination of the results of treatment, or to determine the safety and compatibility with potential recipients.

(2) Specimen receptacles which are devices specifically intended for the primary containment and preservation of specimens derived from the human body are also considered to be *in vitro*diagnostic medical devices.

(3) Devices for general laboratory use are not *in vitro*diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for *in vitro*diagnostic examination.

§ 7. Medical device for self-testing

Medical device for self-testing means an *in vitro*diagnostic medical device intended to be used by lay users.

§ 8. Custom-made medical device

(1) Custom-made medical device means any medical device specifically made in accordance with an order submitted by a professional user which is intended for the sole use of a particular patient.

(2) Mass-produced devices which need to be adapted to meet the specific requirements of a professional user are not considered to be custom-made devices.

§ 9. Medical device subject to clinical investigation

A medical device subject to clinical investigation is a medical device clinically investigated by a professional user.

§ 10. Medical device for performance evaluation

A medical device for performance evaluation is an *in vitro* diagnostic medical device intended by the manufacturer for evaluating the performance of a medical device through one or several tests to be conducted in a laboratory engaged in medical analysis or another appropriate environment not connected to the manufacturer's production activities.

§ 10¹. Medical device subcategory

Medical device subcategory is a set of devices having common areas of intended use or common technology. [RT I, 30.11.2010, 11 – entry into force 10.12.2010]

§ 10². Generic medical device group

Generic medical device group is a set of devices having the same or similar intended uses or commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics. [RT I, 30.11.2010, 11 – entry into force 10.12.2010]

§ 10³. Single use medical device

A single use medical device is a medical device intended to be used once only for a single patient. [RT I, 30.11.2010, 11 – entry into force 10.12.2010]

§ 11. User of medical device

(1) A lay user of a medical device is a person who uses a medical device without the supervision of a health care provider.

(2) A professional user of a medical device is a person who uses a medical device for obtaining clinical evidence in the process of provision of health care services, and in study, science or research.

§ 12. Intended purpose of medical device

14.02.2011 15:51

Correction – the word «*otstarbekohane*» has been replaced with «*sihtotstarbekohane*» in Estonian. Basis: § 10 (4) of *Riigi Teataja* Act.

For the purpose of this Act, the use of a medical device for intended purposes shall mean the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions and/or in promotional materials.

[RT I, 30.11.2010, 11 – entry into force 10.12.2010]

§ 13. Sterilisation of medical device

For the purpose of this Act, sterilisation of a medical device shall mean the cleaning of the device from infectious agents.

§ 14. Notified body

(1) A notified body shall mean a conformity assessment body which has the right to conduct the conformity assessment procedures required for the assessment and attestation of conformity of medical devices.

(2) Product Conformity Act shall be applied, with the specifications arising from this Act, to the notified body and the activities thereof, grant of activity licence to the notified body, suspension of validity or revocation thereof and exercising state supervision over the notified body.

[RT I 2010, 31, 158 – entry into force 01.10.2010]

§ 15. Liability of manufacturer of medical device

(1) The manufacturer of a medical device shall be liable for the conforming design, manufacture, packaging and labelling of a medical device, regardless of whether these operations are carried out by themselves or on their behalf by a third party.

(2) The liability established in this Act to be met by the manufacturer of a medical device also applies to the person who assembles, packages, processes, fully refurbishes or labels one or more ready-made products or assigns to them their intended purpose as a device with a view to their being placed on the market under his or her own name.

(3) Subsection (1) of this section does not apply to the person who assembles or adapts devices already on the market to their intended purpose for an individual patient.

[RT I, 30.11.2010, 11 – entered into force 10.12.2010]

Chapter 2

PLACING ON MARKET AND PUTTING INTO SERVICE OF MEDICAL DEVICES

§ 16. Requirements for placing on market and putting into service of medical devices

(1) A medical device shall be placed on the market and put into service only if:

- 1) the device meets the requirements of this Act and legislation established on the basis thereof;
- 2) a clinical evaluation has been provided for the device, and where necessary, a clinical investigation of the device has been conducted;
- 3) conformity assessment of the device has been carried out;
- 4) the device is accompanied by conforming information necessary for identification of the manufacturer and for the safe use of the device for its intended purpose.

[RT I, 30.11.2010, 11 – entered into force 10.12.2010]

(1¹) For the purposes of this Act, putting into service of a medical device means the making available of a medical device to the end user for use on the market of the European Economic Area for the first time for its intended purpose.

[RT I, 15.04.2014, 1 – entry into force 01.05.2014]

(2) The minister responsible for the area has the right, if a reasoned request to this effect has been submitted, to permit the placing on the market and use of individual medical devices, the conformity of which has not been assessed, provided that the use of such devices is absolutely necessary for the protection of public health.

(3) The information strictly necessary for the safe use of a medical device for its intended purpose accompanying a medical device to be placed on the market, distributed and put into service in Estonia shall be presented in the Estonian language and in an appropriate manner, taking account of the knowledge of the potential user of the device. The remaining information accompanying a device may be presented in another language of a Member State of the European Economic Area understandable to the potential user. The person who places the medical device on the market in Estonia or the distributor shall ensure the correctness of translation of the instructions of a medical device.

[RT I, 30.11.2010, 11 – entry into force 10.12.2010]

§ 16¹. Restrictions on placing on market of medical devices

Non-electric or non-electronic medical devices with measuring function which contain mercury and are intended for lay users shall not be placed on the market.

[RT I, 30.11.2010, 11 – entry into force 10.12.2010]

§ 17. Requirements for medical devices

(1) A medical device shall be designed, manufactured, packaged and labelled such that:

- 1) when the device achieves the performances intended by the manufacturer, its use for its intended purpose is guaranteed;
- 2) the device, if correctly installed and used under prescribed conditions, does not cause the quality of treatment to deteriorate, or pose a risk to the life, health or property of the patient, lay user or third person;
- 3) the benefit to the health of the patient outweighs the potential risks related to using the device.

(2) The requirements for the design, production and packaging of medical devices, and the information to accompany medical devices shall be established by a regulation of the minister responsible for the area.

[RT I, 15.04.2014, 1 – entry into force 01.05.2014]

§ 18. Presentation of non-conforming medical devices

A medical device which does not conform to the requirements specified in § 16 of this Act may be presented at exhibitions and other trade events on condition that the medical device is accompanied by clearly visible information which states that the device must not be placed on the market or put into service until it has been brought into conformity with the requirements specified in this Act and legislation established on the basis thereof.

§ 19. Classification of medical devices

(1) In order to enable the application of the correct procedure for conformity assessment, a manufacturer is required to classify medical devices. Medical devices are divided into classes based on the potential danger to the life and health of persons presented by the devices, and on the intended purpose of the devices.
[RT I, 30.11.2010, 11 – entry into force 10.12.2010]

(2) Medical devices, except *in vitro* diagnostic medical devices and active implantable medical devices, shall be divided into four classes: I, II a, II b and III.

(3) *In vitro* diagnostic medical devices are classified as:
1) medical devices which present a low risk to the patient;
2) medical devices which present a risk to the patient.

(4) The medical devices specified in clause (3) 2) of this section are divided into list A and list B devices.

(5) Active implantable medical devices are not classified and they are deemed to be medical devices which present a risk.

(6) The rules for classification of medical devices shall be established by a regulation of the minister responsible for the area.

[RT I, 15.04.2014, 1 – entry into force 01.05.2014]

(7) If the manufacturer and the notified body disagree on the appropriate application of the classification rules, the matter shall be referred to the Health Board who shall decide on the classification of the device.

§ 20. Clinical evaluation of medical devices

(1) In order to verify conformity of a medical device to the requirements specified in § 17 of this Act upon specific use of the device and to determine any undesirable side-effects produced by the medical device, the manufacturer shall provide a clinical evaluation of the medical device before a conformity assessment is conducted.

(2) A clinical evaluation is based on the evaluation of clinical data taking account of the relevant harmonised standards, if necessary. Upon the evaluation of clinical data, a determined and methodologically justified procedure shall be observed which is based on:

- 1) the critical evaluation of relevant scientific literature on the safety, performance, characteristics of design and intended purpose of the medical device attesting the equivalence of the medical device to the medical device on which the information has been submitted and which proves the conformity of a medical device to the requirements under § 17 (2) of this Act or other essential requirements established in other relevant Acts, or
- 2) the critical evaluation of the results of clinical investigations of medical devices, or
- 3) the critical evaluation of combined clinical data specified in clauses 1) and 2) of this subsection.

(3) Clinical data is information received upon the use of a medical device concerning the safety and performance of the medical device. Clinical data is received from the following sources:

- 1) clinical investigation(s) of the medical device; or
- 2) clinical investigation(s) or other studies reported in the scientific literature, of a similar device for which equivalence to the device in question can be demonstrated; or
- 3) published and/or unpublished reports on other clinical experience of either the device in question or a similar device for which equivalence to the device in question can be demonstrated.

(4) Clinical evaluation and the results thereof shall be documented. Such documents are part of the technical documentation of a medical device or a reference has been made thereto in the technical documentation.

(5) After a medical device has been put into service, the manufacturer of a medical device shall update the clinical evaluation and relevant documentation with information received from the users of the medical device as the result of follow-up inspection. If the manufacturer of a medical device does not consider the follow-up inspection necessary, it must be justified and documented as required.

(6) If the manufacturer of a medical device does not consider it necessary to verify the compliance of a medical device with the requirements specified in § 17 of this Act on the basis of clinical data, he or she shall prepare a statement of grounds based on the results of risk management, taking account of the peculiarities upon contact of the device with body as well as the clinical performance of the medical device. Verification of conformity just based on the performance of the medical device, software testing and preclinical evaluation shall be justified as required.

(7) The persons involved in providing clinical evaluation shall guarantee the confidentiality of information.
[RT I, 30.11.2010, 11 – entry into force 10.12.2010]

§ 21. Clinical investigation of medical devices

(1) The objective of clinical investigation of a medical device is to establish:

- 1) the performance of the medical device;
- 2) the compliance of the medical device with the requirements specified in § 17 of this Act;
- 3) any undesirable side-effects in order to assess the danger created thereby compared to the intended performance of the device.

(2) The clinical investigation of a medical device shall be performed in case of implantable medical devices and class III medical devices, unless reliance on existing clinical data has been justified as required. The clinical investigation of a medical device may prove to be necessary regardless of the risk class of the medical device.

(3) The clinical investigation of a medical device shall only be conducted in case the testing of a medical device on a human being is the only way to receive information on the efficiency, safety and clinical use of the medical device.

(4) A device used in the clinical investigation of a medical device shall be manufactured pursuant to the requirements specified in this Act and in the legislation established on the basis thereof.

(5) The clinical investigation of a medical device shall be conducted on the basis of a relevant investigation plan based on the latest scientific and technical knowledge in a manner which either confirms or rejects the statements of the manufacturer concerning the medical device.

(6) The investigation plan of a medical device shall comply with the following requirements:

- 1) the investigation shall include a sufficient number of observations in order to ensure the scientific validity of the conclusions;
- 2) the investigation procedures shall be suited to the medical device under observation;
- 3) the investigation shall be conducted under the same conditions as the usual conditions of use of the medical device;
- 4) all characteristics, including those connected with safety and performance, shall be investigated, as well as the effect of the medical device on the patient.

(7) In view of ethical considerations, the clinical investigation of a medical device shall be conducted in compliance with the Declaration of Helsinki of the World Medical Association.

(8) The results of the clinical investigation of a medical device are confidential.

(9) Disclosure of information concerning the investigation to the potential participant in the investigation or performance of acts connected with the investigation shall be deemed as the beginning of clinical investigation of the medical device.

(10) The conditions and procedure for conduct of clinical investigation of medical devices shall be established by a regulation of the minister responsible for the area.
[RT I, 30.11.2010, 11 – entry into force 10.12.2010]

§ 21¹. Person conducting clinical investigation of medical devices and obligations of persons connected with investigation

(1) The manufacturer of a medical device or an authorised representative thereof shall ensure the compliance of the investigation as well as all aspects for the conduct thereof.

(2) The clinical investigation of a medical device shall be conducted by the professional user of the medical device.

(3) The professional user conducting the clinical investigation of a medical device shall ensure that the investigation is conducted according to the investigation plan.

(4) The manufacturer of a medical device or an authorised representative thereof shall ensure that the professional user conducting the clinical investigation has access to all technical and clinical data concerning the device.

(5) The professional user conducting the clinical investigation of a medical device and the manufacturer of a medical device or an authorised representative thereof shall register all significant side-effects and shall promptly give written notice thereof to the Health Board and the competent authorities of the Member States of the European Economic Area in which the clinical investigation is conducted.

(6) The professional user conducting the clinical investigation of a medical device and the manufacturer of a medical device or an authorised representative thereof shall give written notice to the Health Board and the competent authorities of the Member States of the European Economic Area in which the clinical investigation is conducted of all changes in the investigation plan and conduct of investigation.

(7) The professional user conducting the clinical investigation of a medical device shall, within his or her competence, provide necessary assistance to the person participating in the investigation. If necessary, the professional user conducting the investigation shall ensure the availability of assistance of other competent health care providers to the person participating in the investigation.

(8) The professional user conducting the clinical investigation of a medical device shall inform the person participating in the investigation and in the cases specified in this Act, the legal representative of the person participating in the investigation, of the circumstances connected with the clinical investigation of the medical device, including of all possible risks and the manner and rate of compensation for personal injuries connected with the investigation.

(9) The manufacturer of medical device or an authorised representative thereof shall ensure the insurance cover of the persons participating in the investigation in case of personal injuries arising from the investigation.

(10) The report of clinical investigation signed by the professional user having conducted the clinical investigation shall include the critical evaluation of all information gathered in the course of investigation.

(11) The manufacturer of a medical device or an authorised representative thereof shall ensure that the Health Board has access to the documents connected with the clinical investigation of a medical device in his or her possession, including the written report of the investigation which includes the critical evaluation of information gathered in the course of investigation.

(12) The manufacturer of a medical device or an authorised representative thereof shall notify the Health Board of termination of the clinical investigation.

[RT I, 30.11.2010, 11 – entry into force 10.12.2010]

§ 21². Consent for participation in clinical investigation of medical devices

(1) In order to participate in the clinical investigation of a medical device, the consent of the person participating in the investigation is required. Consent shall be granted in written form after the participant has been notified of all circumstances related to the clinical investigation of a medical device. The consent may be withdrawn at any time.

(2) For the participation in a clinical investigation of a medical device of a person with restricted active legal capacity, the consent shall be granted by the legal representative of the person with restricted active legal capacity, taking account of his or her presumed will. If the decision of the legal representative evidently damages the interests of the person with restricted active legal capacity, the person conducting the investigation shall not adhere to it. The person with restricted active legal capacity shall be notified of the circumstances of the investigation and of the adopted decisions in reasonable extent. In order for a 7–17-year-old minor to participate in the investigation, his or her consent shall also be required.

(3) A person who is unable to grant his or her informed consent may participate in a clinical investigation of a medical device only if the investigated medical device may be of direct help to him or her and if the objective of the investigation cannot be achieved with an investigation in which the persons participating in it are able to grant their informed consent.

[RT I, 30.11.2010, 11 – entry into force 10.12.2010]

§ 22. Application for right to conduct clinical investigation of medical device, grant of and refusal to grant permit for conduct of investigation, suspension and termination of clinical investigation

(1) In order to conduct a clinical investigation of a medical device for human use, the manufacturer of a medical device or an authorised representative thereof shall obtain the approval of the medical ethics committee for clinical investigations pursuant to the procedure and conditions established by the Medicinal Products Act, taking account of the specifications of this Act.

(2) Permit for the conduct of clinical investigation of a medical device shall be granted by the Health Board. Permit for the conduct of clinical investigation of a medical device used only in veterinary medicine shall be granted according to the Animal Protection Act.

(3) In order to conduct a clinical investigation of a medical device, the manufacturer of a medical device or an authorised representative thereof shall submit an application to the Health Board:

1) at least sixty days before the beginning of the planned investigation in the case of an implantable medical device, active implantable medical device, class III medical device or class II a and II b invasive medical device intended for long-term use;

2) at least ten days before the beginning of the planned investigation in the case of a medical device unspecified in clause 1) of this section.

(4) The Health Board shall decide the grant of or refusal to grant the permit for the conduct of clinical investigation of a medical device, taking account of the considerations connected with human health or public order:

- 1) within sixty days after the date of receipt of all requisite documentation in the case of an implantable medical device, active implantable medical device, class III medical device or class II a and II b invasive medical device intended for long-term use;
- 2) within ten days after the date of receipt of all requisite documentation in the case of a medical device unspecified in clause 1) of this section.

(5) If the Health Board has not, within the term specified in subsection (4) of this section, notified the applicant of refusal to grant the permit or required any additional information from the applicant, the permit shall be deemed to be granted.

(6) The Health Board may refuse to grant the permit for the conduct of clinical investigation in case at least one of the following circumstances exist:

- 1) the applicant does not meet the requirements of clinical investigation of a medical device;
- 2) the information or documents submitted by the applicant are inadequate or incorrect;
- 3) the investigation plan is inexpedient;
- 4) the investigation has no scientific value or may have an irrational effect on the use of the medical device upon provision of health care services;
- 5) the risk on the life and health of the person participating in the investigation is big.

(7) The Health Board shall, on its own initiative, suspend or terminate immediately the clinical investigation of a medical device in case of any circumstance specified in subsection (6) of this section has become evident in the course of investigation, except in the case specified in subsection (8) of this section.

(8) If the continuation of clinical investigation of a medical device does not pose any danger to the life or health of the participants in the investigation, the Health Board shall inform the person conducting the investigation of its intention to suspend or terminate the investigation and shall reason its decision.

(9) The person conducting the clinical investigation of a medical device shall be entitled, within seven days after receipt of the notice specified in subsection (8) of this section, to submit its opinion on suspension or termination of the investigation to the Health Board.

(10) The person conducting the clinical investigation of a medical device shall suspend or terminate the investigation immediately after receipt of the relevant decision of the Health Board.

(11) Subsections (2)-(6) of this section do not apply to medical devices bearing a CE marking of conformity, except in cases where the investigation is carried out without considering the intended purpose of the device.

(12) The information submitted in the application for clinical investigation of a medical device shall be confidential.

[RT I, 30.11.2010, 11 – entry into force 10.12.2010]

§ 23. Assessment of conformity of medical devices

(1) A person wishing to place a medical device on the market under the person's own name shall verify, by way of conformity assessment, that the device manufactured by the person conforms to the requirements applicable thereto, after which the person may prepare a declaration of conformity and affix a CE marking of conformity to the medical device. A CE marking is not affixed to medical devices subject to clinical investigation, custom-made medical devices and medical devices for performance evaluation.

(2) The procedure for conformity assessment of medical devices shall be established by a regulation of the Government of the Republic.

(3) After conducting a conformity assessment, the notified body shall issue a certificate of conformity, or an appendix to the certificate certifying the conformity of the medical device or quality system.

(4) The notified body has the right to suspend or revoke a certificate of conformity if the person specified in subsection (1) of this section does not meet or has ceased to meet the requirements of this Act or legislation established on the basis thereof or if the certificate of conformity should not have been issued. A certificate of conformity is not suspended or revoked if the manufacturer has applied measures which eliminate the non-conformity.

§ 24. Systems of medical devices and procedure packs

(1) Any person who puts together devices bearing the CE marking, taking account of their intended purpose determined by the manufacturers thereof, in order to place them on the market as a system or procedure pack, shall draw up a declaration by which he or she states that:

[RT I, 30.11.2010, 11 – entry into force 10.12.2010]

- 1) he or she has verified the mutual compatibility of the devices in accordance with the manufacturers' instructions;
- 2) he or she has carried out the manufacturer's instructions upon putting the devices together;
- 3) he or she has packaged the system or procedure pack and supplied relevant information to users incorporating relevant instructions from the manufacturers;
- 4) the whole activity of putting together the devices is subjected to appropriate methods of internal control and inspection.

(2) Where the conditions specified in subsection (1) of this section are not met, as in cases where the system or procedure pack incorporates devices which do not bear a CE marking or where the chosen combination of devices is not compatible in view of their intended purpose, the system or procedure pack shall be treated as a device in its own right and as such be subjected to the relevant requirements pursuant to § 23 of this Act.
[RT I, 30.11.2010, 11 – entry into force 10.12.2010]

(3) Any person who sterilises systems or procedure packs referred to in subsection (1) of this section or other CE-marked medical devices designed by their manufacturers to be sterilised before use, shall, at his or her choice, follow a conformity assessment procedure appropriate for the purpose of obtaining sterility. The person sterilising a device shall draw up a declaration stating that sterilisation has been carried out in accordance with the manufacturer's instructions.

(4) The information accompanying the products specified in subsections (1) and (3) of this section shall include information on each device which has been put together.

(5) The persons specified in subsections (1) and (3) of this section shall keep the declarations at the disposal of the Health Board for a period of five years after the date of preparation of the last medical device or pack of medical devices.
[RT I, 30.11.2010, 11 – entry into force 10.12.2010]

§ 25. Preservation of documentation concerning medical devices

(1) The manufacturer of a medical device shall enable, within five years, and in case of implantable medical device, within fifteen years after the date on which the last device of that particular type was manufactured, access to the Health Board to the following documents accompanying the medical device:

- 1) declaration of conformity of the medical device;
- 2) application submitted to the notified body for assessment of the conformity of the quality system;
- 3) documents describing the design, manufacture and performance of the medical device which enable the conformity of the device to be assessed;
- 4) documents issued by the notified body and reports prepared in the process of inspecting the manufacturer of a medical device.

(2) The manufacturer of a medical device or an authorised representative thereof shall enable, within five years after the date the last medical device of that particular type was manufactured in compliance with the corresponding type-examination certificate, and within fifteen years after the date the last implantable medical device of that particular type was manufactured in compliance with the corresponding type-examination certificate, access to the Health Board to the type-examination certificate, its annexes and all relevant technical documentation, and the documents specified in clause (1) 1) and 4) of this section.

(3) If the manufacturer of a medical device or an authorised representative thereof has not been founded in the European Economic Area, then the person responsible for placing the medical device on the market shall enable, within five years after the date the last medical device of that particular type was manufactured, and within fifteen years after the date the last implantable medical device of that particular type was manufactured, the Health Board access to the technical documentation accompanying the device.
[RT I, 30.11.2010, 11 – entry into force 10.12.2010]

§ 26. Notification of placing of medical devices on market and forwarding of information on medical devices already on market

(1) Any person who places a class I medical device, custom-made medical device, system of medical devices, procedure pack or *in vitro*diagnostic medical device on the market in Estonia, shall notify, at least ten days before the medical device is placed on the market, the Health Board of the intention to place the medical device on the market and of any significant alterations of the medical device.
[RT I, 30.11.2010, 11 – entry into force 10.12.2010]

(2) A person specified in subsection (1) of this section shall also give written notice to the Health Board of the placing on the market of a medical device considered to be a new *in vitro*diagnostic medical device.

(3) A medical device is considered to be a new *in vitro*medical device if:

- 1) an *in vitro*diagnostic medical device with similar parameters has not been available on the market during the past three years;
- 2) an examination to be carried out with the aid of the *in vitro*diagnostic medical device involves the use of analytical technology which has not been available on the market during the past three years.

(3¹) Any person who places on the market or puts into service a class II a, II b or III medical device or an active implantable medical device or distributes it for the first time or puts it into professional service for the first time in Estonia shall notify the Health Board thereof within ten days after placing on the market, putting into service, distribution for the first time or putting into professional service for the first time of the device.
[RT I, 15.04.2014, 1 – entry into force 01.05.2014]

(3²) In case the information submitted to the Health Board does not meet the requirements or is insufficient, the Health Board shall be entitled to suspend the sale or distribution of the medical device until the deficiencies have been eliminated.
[RT I, 30.11.2010, 11 – entry into force 01.03.2011]

(4) The manufacturer located outside of the European Economic Area is required to appoint an authorised representative for placing a medical device on the market.

(5) The conditions and procedure for notification of placing on the market, putting into service, distribution for the first time and putting into service for the first time of a medical device and of any significant alterations of the medical device shall be established by a regulation of the minister responsible for the area.
[RT I, 15.04.2014, 1 – entry into force 01.05.2014]

§ 27. Information of adverse incidents and investigation of adverse incidents

(1) The manufacturer or an authorised representative thereof shall inform the Health Board and the relevant notified body of any malfunction or deterioration in the characteristics or performance of a medical device, any technical reasons in relation thereto, as well as any inadequacy in the labelling or instructions which:

- 1) have led, are likely to lead, could have led or might have led to the death of a patient, third person or lay user, or to a serious deterioration in his or her state of health;
- 2) are related to a deterioration in the characteristics or performance of a type of medical device which has been repeatedly recalled from the market by the manufacturer.

(2) A distributor of medical devices shall immediately inform the manufacturer of the relevant medical device or an authorised representative thereof of any adverse incident which could have been caused by a malfunction or deterioration in the characteristics or performance of the medical device.

(3) A health care provider shall immediately inform the Health Board and the manufacturer or an authorised representative thereof of the circumstances specified in subsection (1) of this section. An adverse incident shall be also reported if it involves a medical device which, together with other medical devices, forms a system connected to the patient, whereas each device taken separately or in another combination would not cause such incident.

(4) The manufacturer or an authorised representative thereof shall immediately inform the Health Board of any adverse incident which occurs in the course of a clinical investigation of a medical device.

(5) The Health Board shall establish the circumstances underlying each adverse incident and where possible, seek the assistance of the manufacturer for such purpose. The reasons of an adverse incident may also be established by the manufacturer. The manufacturer investigating the circumstances underlying an adverse incident shall inform the Health Board and, if the notified body was involved in the conformity assessment of the medical device which caused the adverse incident, also the notified body in writing of the process and the outcome of the investigation.

(6) The Health Board shall guarantee that all persons involved in the adverse incident are informed of the outcome of the investigation of the adverse incident.

(7) The persons providing information on an adverse incident shall guarantee the protection of the personal information of a patient or lay user and the business secrets of an undertaking which become known to them in the course of processing the adverse incident.

(8) The minister responsible for the area shall establish, by a regulation, the procedure of providing information on adverse incidents, and the format for providing information.

§ 28. Notification of European Commission and Member States of European Economic Area of adverse incidents

(1) In the cases specified in subsections 27 (1), (3) and (4) of this Act, the Health Board shall immediately inform the European Commission and the competent authorities of the Member States of European Economic Area of an adverse incident concerning which a supervisory procedure has been initiated with the aim to withdraw such device from the market, or to prohibit or restrict its placing on the market and putting into service.

(2) Upon notifying the European Commission and the competent authorities of the Member States of European Economic Area of an adverse incident, the Health Board shall specify whether the adverse incident was caused by non-compliance with the requirements, incorrect application of the harmonised standards or inadequacy of the harmonised standards.

§ 29. Medical Devices Database

[RT I, 15.04.2014, 1 – entry into force 01.05.2014]

(1) Medical Devices Database is a database belonging into the state information system which is maintained to register, collect, process, analyse and forward to the European Databank of Medical Devices of data concerning medical devices placed on the market, put into service, distributed for the first time and put into professional service for the first time in Estonia and the data concerning the adverse incidents, clinical investigations and supervision proceedings related thereto in order to ensure the protection of human health against the risks arising from the medical device.

(2) The manufacturer of a medical device or a representative authorised by the manufacturer, importer, distributor, professional user and lay user of a medical device shall submit data to the Medical Devices Database.

(3) The following data shall be processed in the Medical Devices Database:

- 1) the data and documents related to the placing on the market, putting into service, distribution for the first time and putting into professional service for the first time of a medical device in Estonia;
- 2) the data and documents related to the registration and proceedings of adverse incidents of medical devices;
- 3) the data and documents related to clinical investigations and submitted for application for the right to conduct clinical investigations of medical devices;
- 4) the data and documents related to the supervision proceedings of medical devices.

(4) Medical Devices Database and the statutes thereof shall be established by a regulation of the minister responsible for the area.

(5) The chief processor of the Medical Devices Database shall be the Health Board.

[RT I, 15.04.2014, 1 – entry into force 01.05.2014]

§ 30. Accessibility of information and forwarding thereof to European database of medical devices

(1) Based on the information contained in the database specified in subsection 29 (1) of this Act, the Health Board shall forward the following information to the European database of medical devices:

- 1) data on medical devices placed on market in the European Economic Area through Estonia, and the manufacturers of such devices;
- 2) data relating to certificates of conformity issued;
- 3) data on adverse incidents related to medical devices in adherence to the European system for reporting adverse incidents, including data on withdrawal from sale, prohibition or restriction of sale of devices.

(2) The Health Board shall guarantee the accessibility of the information specified in subsection (1) of this section to the competent authorities of the Member States of the European Economic Area.

(3) The persons involved in forwarding the information shall guarantee the confidentiality of the information.

Chapter 3

REQUIREMENTS FOR HEALTH CARE PROVIDERS UPON PROFESSIONAL USE OF MEDICAL DEVICES

§ 31. Requirements for health care providers upon professional use of medical devices

(1) A medical device shall be used professionally only for its intended purpose in compliance with the manufacturer's instructions, taking account of the principles of evidence-based medicine if, after considering, separately for each case, the potential efficacy, benefit and risks of alternative, less dangerous means serving the same purpose, it is found that the benefit to the health of the patient outweighs the potential risks related to using the device.

[RT I, 30.11.2010, 11 – entry into force 10.12.2010]

(2) The possessor of a medical device shall guarantee:

- 1) the existence of the requisite conditions for use and maintenance of the medical device, as prescribed by the manufacturer;

[RT I, 30.11.2010, 11 – entry into force 10.12.2010]

- 2) the existence of the instructions for use of the device at the place the device is used;
- 3) the provision of installation and maintenance work and, where necessary, repair services by a competent person.

§ 32. Prerequisites for use of medical device

(1) Before the professional use of a medical device is commenced, the health care provider shall check the technical condition of the medical device and arrange for the training of the professional user, provided that it is required in the case of a medical device being put into professional service.
[RT I, 15.04.2014, 1 – entry into force 01.05.2014]

(2) In cases where verifying the correct and safe performance of a medical device is required for putting the device into professional service, the health service provider must prepare a report on putting into professional service of the medical device.
[RT I, 15.04.2014, 1 – entry into force 01.05.2014]

Chapter 3¹ **SALE OF MEDICAL DEVICES ON** **BASIS OF MEDICAL DEVICE CARD**

[RT I, 29.11.2013, 1 - entry into force 09.12.2013]

§ 32¹. Sale of medical devices on basis of medical device card

(1) Upon the sale of a medical device on the basis of a medical device card (hereinafter card) the buyer shall be notified of the correct and safe use, preservation conditions and maintenance of the medical device, the hazards and undesirable side-effects that may accompany the use of the device. The buyer's attention shall be drawn to the explanatory notes on the sales packaging of the medical device. The text covering the use of the medical device shall be recorded on the sales packaging of the medical device or to the sheet attached thereto, if necessary. If a sticker is used, it must not conceal important information.

(2) The card is a document issued to a person by a doctor for the prescription of a suitable medical device.

(3) Upon the sale of a medical device on the basis of a card, the seller shall ascertain the suitability of the medical device and ensure the adjustment thereof for the user, if necessary.

(4) The seller of medical devices shall record the complaints submitted on the devices by recording the data on the person who submitted the complaint, the device, essence of the complaint and circumstances in connection with the complaint. The course of resolving the complaint shall be recorded with the seller of the medical device.

[RT I, 29.11.2013, 1 – entry into force 09.12.2013]

Chapter 4 **STATE SUPERVISION**

§ 33. State supervision

[RT I, 13.03.2014, 4 – entry into force 01.07.2014]

(1) State supervision over compliance with the requirements set by this Act and legislation established on the basis thereof shall be exercised by the Health Board.

(2) The Health Board exercises state supervision:

- 1) over the medical devices placed on the market (market supervision);
- 2) over the compliance with the requirements set for notified bodies and manufacturers by this Act and legislation established on the basis thereof;
- 3) over the notification and investigation of adverse incidents;
- 4) over the organisation of clinical investigations;
- 5) in the event of a dispute between the manufacturer and notified body concerning the classification of medical devices;
- 6) over the compliance with the requirements set for health care providers for professional use of medical devices.

[RT I, 13.03.2014, 4 – entry into force 01.07.2014]

§ 34. Special state supervision measures

[RT I, 13.03.2014, 4 – entry into force 01.07.2014]

For the execution of state supervision provided for in this Act, the law enforcement agency may apply the special state supervision measures provided for in §§ 30, 31, 32, 49 and 50 of the Law Enforcement Act on the basis of and pursuant to the procedure provided for in the Law Enforcement Act.

[RT I, 13.03.2014, 4 – entry into force 01.07.2014]

§ 34¹. Specifications for state supervision

(1) The law enforcement agency may apply the measure specified in § 50 of the Law Enforcement Act in the presence of the person subject to inspection, representative or employee thereof.

(2) In case of non-conformity of a medical device with the requirements of this Act and legislation established on the basis thereof, the Health Board shall initiate a supervisory procedure with the aim to withdraw such device from the market or to prohibit or restrict the placing on the market and putting into service thereof. The Health Board shall inform the European Commission and the competent authorities of the Member States of European Economic Area of initiating a supervisory procedure as well as of its course and outcome.

(3) In justified cases, the Health Board has the right to require, within the two years following the placing on the market of a CE marked medical device specified in subsection 26 (2) of this Act, a report from the manufacturer providing information on the device collected upon marketing.

[RT I, 13.03.2014, 4 – entry into force 01.07.2014]

§ 35. Inspection of conformity of medical devices to requirements

(1) In the course of state supervision, the Health Board has the right, in order to inspect the conformity of medical devices or parts thereof which are placed on the market, to obtain, for a reasonable fee, the necessary amount of medical devices or parts thereof from the manufacturer of the medical devices or the person who places the medical devices on the market and, in justified cases, to order assessment services for inspection of the conformity of medical devices or parts thereof.

(2) In the case of justified doubt, the Health Board has the right to prohibit the placing on the market of a medical device for a time limit necessary to conduct a final check of the conformity of the medical device to the requirements.

(3) Assessment services shall be formalised as expert opinions which describe the analysis, and the results of testing and expert analysis.

(4) Based on the outcome of inspection of a medical device, the Health Board has the right to issue a precept in which the Board requires:

- 1) the provision of supplementary information on the use of the device and any dangers related thereto upon placing the device on the market;
- 2) that the manufacturer, authorised representative thereof or person placing the device on the market inform, by a specified time limit, the users of a medical device of dangers related to the use of the medical device placed on the market and the possibility to eliminate such danger;
- 3) withdrawal from the market of a medical device which has proven to be dangerous, and prohibits advertising the device and where necessary, requires the destruction of the medical device.

(5) If the expert finds the medical device to be conforming, the Health Board shall cover the costs of the assessment service ordered for inspection of the medical device, return the medical device or compensate for caused direct financial damage. If the expert finds the medical device to be non-conforming, the costs of the assessment service shall be compensated by the manufacturer, authorised representative thereof or person placing the device on the market, taking account of the precept issued by the Health Board which must include, as an appendix, a copy of the document in proof of the expenses of the person who provided the assessment service.

§ 36. Limit of penalty payment

[RT I, 13.03.2014, 4 – entry into force 01.07.2014]

In the event of failure to comply with a precept, the upper limit of penalty payment imposed pursuant to the procedure provided for in the Substitutive Enforcement and Penalty Payment Act shall be 3200 euros.

[RT I, 13.03.2014, 4 – entry into force 01.07.2014]

§ 37. Contestation of precept or act

[Repealed - RT I, 13.03.2014, 4 – entry into force 01.07.2014]

Chapter 5

LIABILITY

§ 38. Failure to submit information, failure to give notice of changes to information and submission of false information

Failure, by a legal person, to submit information, failure to give notice of changes to information or submission of false information concerning medical devices is punishable by a fine of up to 3,200 euros.

[RT I, 30.11.2010, 11 – entry into force 01.01.2011]

§ 39. Violation of requirements for placing on the market, distribution, putting into service and professional use of medical devices

[RT I, 30.11.2010, 11 – entry into force 10.12.2010]

(1) Violation of the requirements for the placing on the market, distribution, putting into service and professional use of medical devices is punishable by a fine of up to 200 fine units.

[RT I, 30.11.2010, 11 – entry into force 10.12.2010]

(2) The same act, if committed by a legal person, is punishable by a fine of up to 3,200 euros.

[RT I, 30.11.2010, 11 – entry into force 01.01.2011]

§ 40. Proceedings

(1) The General Part of the Penal Code and the Code of Misdemeanour Procedure apply to the misdemeanours provided for in §§ 38 and 39 of this Act.

(2) The Health Board is the extra-judicial body which conducts proceedings in matters of misdemeanours provided for in §§ 38 and 39 of this Act.

Chapter 6 IMPLEMENTING PROVISIONS

§ 41. Use of medical devices placed on market before entry into force of Act

Medical devices which have been placed on the market pursuant to the procedure in force at the time of entry into force of this Act and which are deemed to be safe may be used until the end of their presumed reasonable service life.

§ 41¹. Submission of data to Medical Devices Database

The data specified in subsection 29 (3) of this Act may be submitted to the Health Board on paper or by electronic means until 1 July 2014.

[RT I, 15.04.2014, 1 – entry into force 01.05.2014]

§ 42.–§ 46.[Omitted from this text.]

§ 47. Entry into force of Act

This Act enters into force on 1 December 2004.

¹Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.07.1990, pp. 17–36), amended by 93/42/EEC (OJ L 169, 12.07.1993, p. 1), by 93/68/EEC (OJ L 220, 30.08.1993, p. 1), and by 90/358/EEC (OJ L 7, 01.11.1994, p. 20); Council Directive 93/42/EEC concerning medical devices (OJ L 169, 12.07.1993, p. 1–43), amended by Directive 98/79/EC of the European Parliament and of the Council (OJ L 331, 07.12.1998, p. 1), amended by 2000/70/EC (OJ L 313, 13.12.2000, p. 22), and by 2001/104/EC (OJ L 6, 10.01.2002, p. 50); Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices (OJ L 331, 07.12.1998, p. 1–37), amended by 98/79/EC (OJ L 22, 29.01.1999, p. 75), and by 98/79/EC (OJ L 6, 10.01.2002, p. 70); Commission Directive 2005/50/EC on the reclassification of hip, knee and shoulder joint replacements in the framework of Council Directive 93/42/EEC concerning medical devices (OJ L 210, 12.08.2005, p. 41–43); Directive 2007/47/EC of the European Parliament and of the Council amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market (OJ L 247, 21.09.2007, p. 21–55); Directive 2007/51/EC of the European Parliament and of the Council

amending Council Directive 76/769/EEC relating to restrictions on the marketing of certain measuring devices containing mercury (OJ L 257, 3.10.2007, p. 13–15); Directive 2008/13/EC of the European Parliament and of the Council repealing Council Directive 84/539/EEC on the approximation of the laws of the Member States relating to electro-medical equipment used in veterinary medicine (OJ L 76, 19.03.2008, p. 41); Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare (OJ L 88, 04.04.2011, p. 45–65). [RT I, 29.11.2013, 1 – entered into force 09.12.2013]