Issuer:	Riigikogu
Type:	act
In force from:	01.02.2022
In force until:	31.12.2022
Translation published:	03.02.2022

Medical Devices Act[1]

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, in part 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, 12.07.2014, 1	01.01.2015
19.06.2014	RT I, 29.06.2014, 109	01.07.2014, official titles of ministers replaced on the basis of subsection 107³ (4) of the Government of the Republic Act
19.11.2014	RT I, 13.12.2014, 2	01.01.2016
18.02.2015	RT I, 23.03.2015, 4	01.07.2015
19.11.2015	RT I, 01.12.2015, 2	01.06.2016
13.05.2020	RT I, 17.05.2020, 1	27.05.2020, in part 26.05.2021
15.12.2021	RT I, 03.01.2022, 2	01.02.2022 - enters into force on the date when six months have passed since publishing the notice referred to in Article 82 (2) of Regulation (EU) No 536/2014 of the European Parliament and of the Council in the Official Journal of the European Union, Committee decision (EU) 2021/1240 of 13 July 2021 (OJ L 275, 31.07.2021, p 1–2).]

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) *in vitro*diagnostic medical devices, the accessories thereof (hereinafter *in vitro diagnostic medical device*) and the manufacture thereof;
2) placing on the market and putting into service of medical devices;
3) clinical investigation of medical devices;
4) professional use of medical devices;
5) sale of medical devices on the basis of medical device card;
6) proceeding of an adverse incident of medical devices;
7) state supervision of medical devices.

(2) This Act shall not apply to medical devices in the cases where Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (OJ L 117, 05.05.2017, p 1–175) is applied.

(3) This Act shall not apply to *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.
[RT I, 17.05.2020, 1 – entry into force 26.05.2021]

§ 2. Application of other legal instruments

[RT I, 17.05.2020, 1 – entry into force 26.05.2021]

(1) 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 and Regulation (EU) 2017/745 of the European Parliament and of the Council and Regulation (EU) 2017/746 of the European Parliament and of the Council on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (OJ L 117, 05.05.2017, p 176–332).

(2) The provisions of the Administrative Procedure Act apply to administrative proceedings prescribed in this Act, taking account of the specifications provided for in this Act.
[RT I, 17.05.2020, 1 – entry into force 26.05.2021]

§ 3. Medical device

[Repealed – RT I, 17.05.2020, 1 – entry into force 26.05.2021]

§ 3[1]. Terms

In this Act, the terms are used for the purposes of Regulation (EU) 2017/745 of the European Parliament and of the Council, unless provided otherwise in this Act.
[RT I, 17.05.2020, 1 – entry into force 26.05.2021]

§ 4. Accessory

[Repealed – RT I, 17.05.2020, 1 – entry into force 26.05.2021]

§ 4[1]. Active medical device

[Repealed – RT I, 17.05.2020, 1 – entry into force 26.05.2021]

§ 5. Active implantable medical device

[Repealed – RT I, 17.05.2020, 1 – entry into force 26.05.2021]

§ 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.

§ 6[1]. Accessory for*in vitro*diagnostic medical device

(1) For the purposes of this Act, an accessory for an *in vitro*diagnostic medical device means a device which, whilst not being itself an *in vitro*diagnostic medical device, is intended by its manufacturer to be used together with an *in vitro*diagnostic medical device to specifically enable the *in vitro*diagnostic medical device to be used in accordance with its intended purpose.

(2) An accessory for an *in vitro*diagnostic medical device is not a sampling tool or device inserted into human body, which is in direct contact with the human body during sampling and to which Regulation (EU) 2017/745 of the European Parliament and of the Council applies.
[RT I, 17.05.2020, 1 – entry into force 26.05.2021]

§ 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

[Repealed – RT I, 17.05.2020, 1 – entry into force 26.05.2021]

§ 9. Medical device subject to clinical investigation

[Repealed – RT I, 17.05.2020, 1 – entry into force 26.05.2021]

§ 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.

§ 10[1]. Medical device subcategory

[Repealed – RT I, 17.05.2020, 1 – entry into force 26.05.2021]

§ 10[2]. Generic medical device group

[Repealed – RT I, 17.05.2020, 1 – entry into force 26.05.2021]

§ 10[3]. Single use medical device

[Repealed – RT I, 17.05.2020, 1 – entry into force 26.05.2021]

§ 11. Professional users of medical devices

[RT I, 17.05.2020, 1 – entry into force 26.05.2021]
For the purposes of this Act, 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.
[RT I, 17.05.2020, 1 – entry into force 26.05.2021]

§ 12. Intended purpose of*in vitro*diagnostic medical device

[RT I, 17.05.2020, 1 – entry into force 26.05.2021]
For the purposes of this Act, the use of an *in vitro*diagnostic 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, 17.05.2020, 1 – entry into force 26.05.2021]

§ 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 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, with the specifications arising from this Act and Regulations (EU) 2017/745 and (EU) 2017/746 of the European Parliament and of the Council.
[RT I, 17.05.2020, 1 – entry into force 27.05.2020]

§ 14[1]. Competent authority and authority liable for notified body

The Health Board shall perform the acts of a competent authority and the authority liable for a notified body provided for in this Act and Regulations (EL) 2017/745 and (EL) 2017/746 of the European Parliament and of the Council, and issue administrative acts, unless provided otherwise in the given regulations.
[RT I, 17.05.2020, 1 – entry into force 27.05.2020]

§ 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]

§ 15[1]. Paid services

(1) The Health Board may provide paid services connected with its principal activity for ensuring the compliance with medical devices quality and safety requirements, provided that it does not hinder the performance of its functions arising from the legislation and the provision of paid services is necessary in connection with:
1) the performance of functions provided for in Regulations (EU) 2017/745 and (EU) 2017/746 of the European Parliament and of the Council, taking account of the restrictions established in the given regulations for competent authority and authority liable for notified body, or
2) the prevailing situation on the market regarding the provision of the same services and the provision of service is not restricted by Regulation (EU) 2017/745 or Regulation (EU) 2017/746 of the European Parliament and of the Council.

(2) The Health Board may provide paid services connected with its principal activity for ensuring the compliance with medical devices quality and safety requirements if the aim of providing the service is to give a scientific opinion to a notified body based on Regulation (EU) 2017/745 or Regulation (EU) 2017/746 of the European Parliament and of the Council and the given regulations do not restrict the provision of service.

(3) The fee of the Health Board for the provision of one service may not be more than 15,000 euros and the fee of the State Agency of Medicines for one service may not be more than 20,000 euros.

(4) The list and fee rates of paid services of the Health Board and State Agency of Medicines for ensuring compliance with medical devices quality and safety requirements, taking account of the labour, material, equipment and overall costs necessary for providing the service, shall be established by a regulation of the minister responsible for the area.
[RT I, 17.05.2020, 1 – entry into force 26.05.2021]

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) An *in vitro*diagnostic medical device shall be placed on the market and put into service only if the device meets the requirements of this Act and legislation established on the basis thereof or the requirements of Regulation (EU) 2017/746 of the European Parliament and of the Council.
[RT I, 17.05.2020, 1 – entry into force 26.05.2021]

(1^1) [Repealed – RT I, 17.05.2020, 1 – entry into force 26.05.2021]

(2) The Health Board has the right, if a reasoned request to this effect has been submitted, to permit the placing on the market and use of individual in vitro diagnostic 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.
[RT I, 17.05.2020, 1 – entry into force 27.05.2020]

(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]

§ 16^1. 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*in vitro*diagnostic medical devices

[RT I, 17.05.2020, 1 – entry into force 26.05.2021]

(1) *In vitro*diagnostic medical devices shall be designed, manufactured, packaged and labelled such that:
1) its use for its intended purpose is guaranteed when the device achieves the performances intended by the manufacturer;
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.

(2) The requirements for the design, production and packaging of *in vitro*diagnostic medical devices, and the information to accompany medical devices shall be established by a regulation of the minister responsible for the area.
[RT I, 17.05.2020, 1 – entry into force 26.05.2021]

§ 18. Presentation of non-conforming*in vitro*diagnostic medical devices

[RT I, 17.05.2020, 1 – entry into force 26.05.2021]
An *in vitro*diagnostic 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 the condition that the 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 of this Act and legislation established on the basis thereof.
[RT I, 17.05.2020, 1 – entry into force 26.05.2021]

§ 19. Classification of*in vitro*diagnostic medical devices

[RT I, 17.05.2020, 1 – entry into force 26.05.2021]

(1) In order to enable the application of the correct procedure for conformity assessment, a manufacturer is required to classify *in vitro*diagnostic medical devices. *In vitro*diagnostic 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.

(2) *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.

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

(4) The rules for classification of *in vitro*diagnostic medical devices shall be established by a regulation of the minister responsible for the area.
[RT I, 17.05.2020, 1 – entry into force 26.05.2021]

§ 20. Clinical evaluation of medical devices

[Repealed – RT I, 17.05.2020, 1 – entry into force 26.05.2021]

§ 21. Clinical investigation of medical devices

[Repealed – RT I, 17.05.2020, 1 – entry into force 26.05.2021]

§ 21[1]. Obligations of person conducting clinical investigation of medical devices and persons connected with investigation

(1) The sponsor of clinical investigation of a medical device shall ensure the compliance of the investigation as well as all aspects for the conduct thereof.
[RT I, 17.05.2020, 1 – entry into force 26.05.2021]

(2) The clinical investigation of a medical device shall be conducted by the professional user of the medical device.
[RT I, 30.11.2010, 11 – entry into force 10.12.2010]

(3) The professional user conducting the clinical investigation of a medical device shall ensure that the investigation is conducted according to the investigation plan.
[RT I, 30.11.2010, 11 – entry into force 10.12.2010]

(4) The sponsor of clinical investigation of medical device shall ensure that the professional user conducting the clinical investigation has access to all technical and clinical data concerning the device.
[RT I, 17.05.2020, 1 – entry into force 26.05.2021]

(5) The professional user conducting the clinical investigation of a medical device and the sponsor of clinical investigation of a medical device 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.
[RT I, 17.05.2020, 1 – entry into force 26.05.2021]

(6) The professional user conducting the clinical investigation of a medical device and the sponsor of clinical investigation of medical device 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.
[RT I, 17.05.2020, 1 – entry into force 26.05.2021]

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

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

(9) The sponsor of clinical investigation of a medical device shall ensure the insurance cover of the persons participating in the investigation in case of personal injuries arising from the investigation.
[RT I, 17.05.2020, 1 – entry into force 26.05.2021]

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

(11) The sponsor of clinical investigation of a medical device 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.
[RT I, 17.05.2020, 1 – entry into force 26.05.2021]

(12) The sponsor of clinical investigation of a medical device shall notify the Health Board of termination of the clinical investigation.
[RT I, 17.05.2020, 1 – entry into force 26.05.2021]

§ 21[2]. Consent for participation in clinical investigation of medical devices

In order to participate in the clinical investigation of a medical device, the consent of the person participating in the investigation is required, which must comply with Regulation (EU) 2017/745 of the European Parliament and of the Council. The consent of a minor is required for participation of a 7–17-year-old minor in the investigation.
[RT I, 17.05.2020, 1 – entry into force 26.05.2021]

§ 21[3]. Independent medical ethics committee

(1) Independent medical ethics committee (hereinafter *ethics committee*) means the independent body composed of scientists and representatives from different fields of life empowered to give opinions for conducting clinical investigations of a medical device and whose objective is to ensure the protection of rights, safety and wellbeing of the participants in the investigation.

(2) The ethics committee shall assess the application for clinical investigation of a medical device and substantial modification of the investigation and upon giving their opinion shall be guided from the requirements provided for in Regulation (EU) 2017/745 of the European Parliament and of the Council.

(3) In their activity the ethics committee shall be guided from the established ethical requirements and international conventions and also the principles provided for in Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 04.05.2016, p 1–88) and in specific law.

(4) The ethics committee shall assess the size of ethical risks of the clinical investigation of a medical device and the background of the investigator, finding a balance between the protection of fundamental rights and the expedience of the investigation.

(5) The rules of procedure of the ethics committee, the number of members and procedure for the appointment of members and the term of authority of the members shall be established by a regulation of the minister responsible for the area.

(6) The membership of the ethics committee and the experts involved in the work of the ethics committee shall be published on the website of the ethics committee.
[RT I, 03.01.2022, 2 – entry into force 01.02.2022 - enters into force on the date when six months have passed since publishing the notice referred to in Article 82 (2) of Regulation (EU) No 536/2014 of the European Parliament and of the Council in the *Official Journal of the European Union*, Committee decision (EU) 2021/1240 of 13 July 2021 (OJ L 275, 31.07.2021, p 1–2).]

§ 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 and make a substantial modification of the investigation, the sponsor of clinical investigation of a medical device shall obtain the opinion of the ethics committee, taking account of the requirements specified in this Act and Regulation (EU) 2017/745 of the European Parliament and of the Council.
[RT I, 03.01.2022, 2 – entry into force 01.02.2022 – enters into force on the date when six months have passed since publishing the notice referred to in Article 82 (2) of Regulation (EU) No 536/2014 of the European Parliament and of the Council in the *Official Journal of the European Union*, Committee decision (EU) 2021/1240 of 13 July 2021 (OJ L 275, 31.07.2021, p 1–2).]

(1[1]) The sponsor of clinical investigation of a medical device shall pay a fee to the ethics committee for giving an ethical opinion on the application for clinical investigation of a medical device and notifying of substantial modifications of an investigation.
[RT I, 03.01.2022, 2 – entry into force 01.02.2022 - enters into force on the date when six months have passed since publishing the notice referred to in Article 82 (2) of Regulation (EU) No 536/2014 of the European Parliament and of the Council in the *Official Journal of the European Union*, Committee decision (EU) 2021/1240 of 13 July 2021 (OJ L 275, 31.07.2021, p 1–2).]

(1^2) The fee specified in subsection (11) of this section shall be determined by the ethics committee on the basis of the following conditions:
1) the fee cannot be more than 3000 euros;
2) the size of the fee has been determined based on the costs related with the delivery of an opinion;
3) the size of the fee has been made publicly available.
[RT I, 03.01.2022, 2 – entry into force 01.02.2022 - enters into force on the date when six months have passed since publishing the notice referred to in Article 82 (2) of Regulation (EU) No 536/2014 of the European Parliament and of the Council in the *Official Journal of the European Union*, Committee decision (EU) 2021/1240 of 13 July 2021 (OJ L 275, 31.07.2021, p 1–2).]

(2) Permit for the conduct of clinical investigation of a medical device shall be granted by the Health Board.
[RT I, 17.05.2020, 1 – entry into force 26.05.2021]

(2^1) Before the submission of an application, the sponsor of clinical investigation of a medical device applying for the permit of clinical investigation of a medical device shall be required to pay state fee for review of the application with the rate provided for in the State Fees Act.
[RT I, 17.05.2020, 1 – entry into force 26.05.2021]

(3) In order to conduct a clinical investigation of a medical device, the sponsor of clinical investigation of a medical device shall submit an application to the Health Board:
[RT I, 17.05.2020, 1 – entry into force 18.05.2020]
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.
[RT I, 30.11.2010, 11 – entry into force 10.12.2010]

(3^1) The sponsor of clinical investigation of a medical device shall, together with the application for clinical investigation of a medical device and notification of substantial modifications of the investigation, also submit the opinion to the ethics committee to the Health Board.
[RT I, 03.01.2022, 2 – entry into force 01.02.2022 - enters into force on the date when six months have passed since publishing the notice referred to in Article 82 (2) of Regulation (EU) No 536/2014 of the European Parliament and of the Council in the *Official Journal of the European Union*, Committee decision (EU) 2021/1240 of 13 July 2021 (OJ L 275, 31.07.2021, p 1–2).]

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

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

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

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

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

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

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

(11) Subsections (2)-(6) of this section do not apply to medical devices bearing a CE marking, except in cases where the investigation is carried out without considering the intended purpose of the device.
[RT I, 01.12.2015, 2 - entry into force 01.06.2016]

(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]

(13) The list of data and documents submitted for the conduct of clinical investigation of a medical device and the conditions and procedure for submission of an application for the conduct of investigation, commencement of investigation, making changes in the investigation plan, preservation of data connected with the investigation and termination of the investigation shall be established by a regulation of the minister responsible for the area.
[RT I, 17.05.2020, 1 – entry into force 26.05.2021]

(14) The persons assessing the application file for clinical investigation of a medical device and confirming the compliance thereof shall submit to the Health Board by 31 May each year the declaration of interests in which they confirm that they have no conflict of interests and financial or other interests which could affect their impartiality.
[RT I, 03.01.2022, 2 – entry into force 01.02.2022 - enters into force on the date when six months have passed since publishing the notice referred to in Article 82 (2) of Regulation (EU) No 536/2014 of the European Parliament and of the Council in the *Official Journal of the European Union*, Committee decision (EU) 2021/1240 of 13 July 2021 (OJ L 275, 31.07.2021, p 1–2).]

§ 23. Assessment of conformity of*in vitro*diagnostic medical devices

[RT I, 17.05.2020, 1 – entry into force 26.05.2021]

(1) A person wishing to place an *in vitro*diagnostic 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 device. A CE marking is not affixed to medical devices for performance evaluation.

(11) The CE marking must be affixed on the instructions for use of the *in vitro*diagnostic medical device in a visible, legible and indelible form and, if applicable, on the device or the sterile packaging thereof. The CE marking must also be affixed on the sales packaging of the device, if applicable.

(2) The procedure for conformity assessment of *in vitro*diagnostic medical devices shall be established by a regulation of the minister responsible for the area.

(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 *in vitro*diagnostic medical device or quality system. In this case the CE marking must be accompanied with the identification code of the notified body.

(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.
[RT I, 17.05.2020, 1 – entry into force 26.05.2021]

§ 24. Systems of medical devices and procedure packs

[Repealed – RT I, 17.05.2020, 1 – entry into force 26.05.2021]

§ 25. Preservation of documents concerning*in vitro*diagnostic medical devices

[RT I, 17.05.2020, 1 – entry into force 26.05.2021]

(1) The manufacturer of an *in vitro*diagnostic medical device shall enable, within five 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 device:
1) declaration of conformity of the *in vitro*diagnostic 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 *in vitro*diagnostic 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 an *in vitro*diagnostic medical device.

(2) The manufacturer of an *in vitro*medical device or an authorised representative thereof shall enable, within five years after the date the last 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 clauses (1) 1) and 4) of this section.

(3) If the manufacturer of an *in vitro*diagnostic medical device or an authorised representative thereof has not been founded in the European Economic Area, then the person responsible for placing the device on the market shall enable, within five years after the date the last device of that particular type was manufactured, the Health Board access to the technical documentation accompanying the device.
[RT I, 17.05.2020, 1 – entry into force 26.05.2021]

§ 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.

(3^1) Any person who distributes for the first time in Estonia or puts into professional service a class II a, II b or III medical device or an active implantable medical device shall notify the Health Board thereof within ten days after distribution for the first time or putting into professional service of the device.
[RT I, 01.12.2015, 2 - entry into force 01.06.2016]

(3^2) 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 lead or might have lead 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 sponsor of clinical investigation of a medical device shall immediately inform the Health Board of any adverse incident which occurs in the course of a clinical investigation of a medical device.
[RT I, 17.05.2020, 1 – entry into force 26.05.2021]

(5) The requirements arising from Regulation (EU) 2017/745 of the European Parliament and of the Council must be complied with upon the investigation of adverse incidents of medical devices, except for an *in vitro*diagnostic medical device. In case of an *in vitro*diagnostic medical device adverse incident, the Health Board shall establish the circumstances underlying each adverse incident and where possible, seek the assistance of the manufacturer for such purpose. The cause of an *in vitro*diagnostic medical device adverse incident may also be established by the manufacturer. The manufacturer investigating the circumstances underlying an adverse incident of an *in vitro*diagnostic medical device shall inform the Health Board and, if the notified body was involved in the conformity assessment of the device which caused the adverse incident, also the notified body in writing of the process and the outcome of the investigation.
[RT I, 17.05.2020, 1 – entry into force 26.05.2021]

(6) The Health Board shall guarantee that all persons involved in the adverse incident of an *in vitro*diagnostic medical device are informed of the outcome of the investigation of the adverse incident.
[RT I, 17.05.2020, 1 – entry into force 26.05.2021]

(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 and Appliances Databaseu

[RT I, 13.12.2014, 2 - entry into force 01.01.2016]

(1) The Medical Devices and Appliances 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, the data concerning the adverse incidents, clinical investigations and supervision proceedings related thereto, the data concerning the assumption of the fee payment obligation by the Estonian Health Insurance Fund (hereinafter compensation) and the data concerning the purchase and rental of appliances for the purposes of the Social Welfare Act in order to protect the human health against the risks arising from the medical devices and to ensure access to the medical devices and appliances to be compensated for.

(2) The data to the Medical Devices and Appliances Database shall be submitted by:
1) the manufacturer of a medical device or a representative authorised by the manufacturer;
2) the importer of a medical device;
3) the distributor of a medical device;
4) the professional user of a medical device;
5) the lay user of a medical device;
6) the seller and lessor of an appliance;
7) the Estonian Health Insurance Fund.

(3) The following data shall be processed in the Medical Devices and Appliances 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 averse incidents of medical devices;
3) the data and documents related to clinical investigations and submitted for the application for the right to conduct clinical investigations of medical devices;
4) the data and documents related to the supervision proceedings of medical devices;
5) the retail and rental prices of appliances, the contact information of the place of provision of services and the description of products;
6) the data and documents related to the compensation for medical devices.

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

(5) The controller of the Medical Devices and Appliances Database shall be the Health Board.
[RT I, 13.12.2014, 2 - entry into force 01.01.2016]

§ 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 3^1
SALE OF MEDICAL DEVICES ON BASIS OF MEDICAL DEVICE CARD

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

§ 32[1]. 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 3[2]
CERTIFICATE OF FREE SALE

[RT I, 17.05.2020, 1 - entry into force 26.05.2021]

§ 32[2]. Issue of certificate of free sale

(1) For the purpose of export and upon request by a manufacturer or an authorised representative, the Health Board shall issue a certificate of free sale, declaring that the manufacturer or the authorised representative has its registered place of business in the territory of the Republic of Estonia and that the device in question bearing the CE marking may be marketed in the European Union.

(2) A certificate of free sale shall be issued on the conditions and pursuant to the procedure provided for in Regulation (EU) 2017/745 of the European Parliament and of the Council.

(3) The manufacturer or an authorised representative applying for a certificate of free sale are required, before submitting an application, pay state fee for the review of application with the rate provided for in the State Fees Act.
[RT I, 17.05.2020, 1 – entry into force 26.05.2021]

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 established in this Act and legislation established on the basis thereof and in Regulations (EU) 2017/745 and (EU) 2017/746 of the European Parliament and of the Council shall be exercised by the Health Board.
[RT I, 17.05.2020, 1 – entry into force 27.05.2020]

(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]

§ 34[1]. 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, 01.12.2015, 2 - entry into force 01.06.2016]

§ 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 *in vitro*diagnostic medical devices or parts thereof which are placed on the market, to obtain, for a reasonable fee, the necessary amount of *in vitro*diagnostic medical devices or parts thereof from the manufacturer of the *in vitro*diagnostic medical devices or the person who places the *in vitro*diagnostic medical devices on the market and, in justified cases, to order assessment services for inspection of the conformity of in vitro diagnostic medical devices or parts thereof.
[RT I, 17.05.2020, 1 – entry into force 26.05.2021]

(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 non-compliance levy

[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 non-compliance levy imposed pursuant to the procedure provided for in the Substitutional Performance and Non-Compliance Levies 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

[Repealed – RT I, 12.07.2014, 1 - entry into force 01.01.2015]

§ 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]

§ 39[1]. Violation of requirements for conduct of clinical investigation of medical devices

(1) Violation of the requirements for the conduct of clinical investigation of medical devices is punishable by a fine of up to 300 fine units.

(2) The same act, if committed by a legal person, is punishable by a fine of up to 32,000 euros.
[RT I, 17.05.2020, 1 – entry into force 27.05.2020]

§ 40. Proceedings

The Health Board is the extra-judicial body which conducts proceedings in matters of misdemeanours provided in this chapter.
[RT I, 12.07.2014, 1 - entry into force 01.01.2015]

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.

§ 41[1]. 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.

[1]Council 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]