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# 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 4 of § 107³ 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). |
| 07.12.2022 | RT I, 22.12.2022, 2 | 01.01.2023 |

# Chapter 1
# GENERAL PROVISIONS

**§ 1. Scope of application of Act**

(1) This Act regulates the placing on the market, putting into service, making available on the market and distribution, clinical investigations and performance studies, professional use and manufacture within institution of medical devices, the sale of medical devices on the basis of medical device card, issue of certificate of free sale, requirements for information related with a medical device and for the submission thereof and state supervision and liability to ensure the safety, quality and efficiency of medical devices used on the people in Estonia and to promote the use thereof for the intended purpose.
[RT I, 22.12.2022, 2 – entry into force 01.01.2023]

(2) This Act is not applied in 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), or 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(ELT L 117, 05.05.2017, p 176–332) applies.
[RT I, 22.12.2022, 2 – entry into force 01.01.2023]

(3) [Repealed − RT I, 22.12.2022, 2 – entry into force 01.01.2023]

**§ 2. Application of other legal instruments**

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

(1) The requirements of the Product Conformity Act are applied to the duties of the manufacturer, their authorised representative, 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 Regulations (EU) 2017/745 and (EU) 2017/746 of the European Parliament and of the Council.
[RT I, 22.12.2022, 2 – entry into force 01.01.2023]

(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 and Regulation (EU) 2017/746 of the European Parliament and of the Council, unless provided otherwise in this Act.
[RT I, 22.12.2022, 2 – entry into force 01.01.2023]

**§ 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**

[Repealed − RT I, 22.12.2022, 2 – entry into force 01.01.2023]

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

[Repealed − RT I, 22.12.2022, 2 – entry into force 01.01.2023]

**§ 7. Medical device for self-testing**

[Repealed − RT I, 22.12.2022, 2 – entry into force 01.01.2023]

**§ 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**

[Repealed − RT I, 22.12.2022, 2 – entry into force 01.01.2023]

**§ 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 in the process of provision of health care or other services, and also in study, science or research.
[RT I, 22.12.2022, 2 – entry into force 01.01.2023]

**§ 11[1]. Ordering custom-made medical devices**

Custom-made medical devices are manufactured according to the special order of a professional user based on the needs of a specific patient.
[RT I, 22.12.2022, 2 – entry into force 01.01.2023]

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

[Repealed − RT I, 22.12.2022, 2 – entry into force 01.01.2023]

**§ 13. Sterilisation of medical device**

[Repealed − RT I, 22.12.2022, 2 – entry into force 01.01.2023]

**§ 14. Notified body**

(1) [Repealed − RT I, 22.12.2022, 2 – entry into force 01.01.2023]

(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**

[Repealed − RT I, 22.12.2022, 2 – entry into force 01.01.2023]

**§ 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 in charge of the policy sector.
[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) [Repealed − RT I, 22.12.2022, 2 – entry into force 01.01.2023]

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

(2) [Repealed − RT I, 22.12.2022, 2 – entry into force 01.01.2023]

(3) The manufacturer, relying on risk analysis, ascertains the information necessary for the safe use of a device for the intended purpose, and the information related with a medical device placed on the market, made available on the market, distributed and put into service in Estonia must be presented:
1) in the Estonian language and in an appropriate manner if the medical device is intended for the use of lay users;
2) in the Estonian or English language and in an appropriate manner if the medical device is intended only for the use of professional users;
3) in the language understandable to a specific user and in an appropriate manner in case of a custom-made medical device.
[RT I, 22.12.2022, 2 – entry into force 01.01.2023]

(4) Differently from the provisions of subsection 3 of this section, the remaining information related with a medical device may be presented in another language of a Member State of the European Union or the European Economic Area that is understandable to potential users.
[RT I, 22.12.2022, 2 – entry into force 01.01.2023]

(5) The declaration of conformity of a medical device distributed in Estonia must be drawn in Estonian or English or translated into Estonian or English.
[RT I, 22.12.2022, 2 – entry into force 01.01.2023]

(6) A notified body registered in Estonia issues the certificates of conformity either in Estonian or English.
[RT I, 22.12.2022, 2 – entry into force 01.01.2023]

**§ 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**

[Repealed − RT I, 22.12.2022, 2 – entry into force 01.01.2023]

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

[Repealed − RT I, 22.12.2022, 2 – entry into force 01.01.2023]

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

[Repealed − RT I, 22.12.2022, 2 – entry into force 01.01.2023]

**§ 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 persons conducting clinical investigations of medical devices and performance studies of *in vitro*diagnostic medical devices (hereinafter investigation) and obligations of persons connected with investigation**

[RT I, 22.12.2022, 2 – entry into force 01.01.2023]

(1) If the investigation is planned to be conducted only in Estonia or only in Estonia and in another state besides the Member State of the European Union or European Economic Area and the sponsor has not been registered in a Member State, the Health Board may, upon the sponsor's request, give permission to the sponsor to establish a contact person in their place in respect of that investigation, based on the provisions of subsection 2 of Article 62 of Regulation (EU) 2017/745 or subsection 4 of Article 58 of Regulation (EU) 2017/746 of the European Parliament and of the Council accordingly.

(2) The Health Board grants the permission specified in subsection 1 of this section, provided that the grant of permission is not accompanied with significant risks to the safety and rights of the participants in the investigation and the requirements provided for in Regulation (EU) 2017/745 or (EL) 2017/746 of the European Parliament and of the Council and in this Act are complied with.

(3) A sponsor who wishes to establish a contact person in their place according to subsection 1 of this section, may submit to the independent ethics committee and the Health Board the application documents for the conduct of investigation (hereinafter application for investigations) after the sponsor has been given the permission to use a contact person.

(4) The sponsor notifies the Health Board at least ten days in advance if they plan to conduct:
1) an investigation specified in Article 74 of Regulation (EU) 2017/745 of the European Parliament and of the Council, where the investigation would involve submitting subjects to procedures additional to those performed under the normal conditions of use of the device and those additional procedures are not invasive or burdensome;
2) a performance study specified in subsection 2 of Article 58 of Regulation (EU) 2017/746 of the European Parliament and of the Council involving companion diagnostics using only left-over samples.

(5) The sponsor ensures the insurance cover for the compensation for any health damage suffered by a subject resulting from participation in the investigation and which covers the liability of the sponsor and investigator and which is appropriate to the nature and extent of the risk. To prove the insurance cover, the sponsor submits the insurance policy or a copy thereof together with the application for investigations.

(6) Where the documents specified in Annex XV of Regulation (EU) 2017/745 or in Annex XIII of Regulation (EU) 2017/746 of the European Parliament and of the Council must be submitted, these may be drawn either in Estonian or English, except for the documents used for obtaining the informed consent which must be drawn in the native language of the participant in the investigation.

(7) A sponsor, their legal representative or contact person must keep available for the competent authorities the information and documents connected with an investigated medical device or the investigation within the time and pursuant to the procedure provided for in point 3 of Chapter III of Annex XV of Regulation (EU) 2017/745 or in point 3 of Chapter II of Annex XIV of Regulation (EU) 2017/746 of the European Parliament and of the Council.
[RT I, 22.12.2022, 2 – entry into force 01.01.2023]

### § 21[2]. Consent for participation in investigation

[RT I, 22.12.2022, 2 – entry into force 01.01.2023]
The informed consent of a subject which corresponds to the Regulation (EU) 2017/745 or (EU) 2017/746 of the European Parliament and of the Council is required for participation in the investigation. The consent of a minor is required for participation of a 7–17-year-old minor in the investigation.
[RT I, 22.12.2022, 2 – entry into force 01.01.2023]

### § 21[3]. Independent ethics committee

[RT I, 22.12.2022, 2 – entry into force 01.01.2023]

(1) An independent ethics committee (hereinafter the ethics committee) is an independent body of scientists and representatives from different fields of life practicing at research and development agencies, empowered to give opinions for conducting investigations and whose objective is to ensure the safety, wellbeing and protection of rights of the participants in the investigation.
[RT I, 22.12.2022, 2 – entry into force 01.01.2023]

(2) The ethics committee gives an opinion on the conduct of an investigation and making substantial modifications to the investigation.
[RT I, 22.12.2022, 2 – entry into force 01.01.2023]

(3) In giving their opinion the ethics committee proceeds from the requirements provided for in Regulation (EU) 2017/745 or (EU) 2017/746 of the European Parliament and of the Council, the standard on good clinical practice for clinical investigations of medical devices applicable in the European Union, the established ethics norms and international conventions and the principles provided for in Regulation (EU) 2016/679 of the European Parliament and of the Council 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 laws.
[RT I, 22.12.2022, 2 – entry into force 01.01.2023]

(4) The ethics committee assesses the size of ethical risks of the investigation and the background of the investigator, finding a balance between the protection of fundamental rights and the expedience of the investigation.
[RT I, 22.12.2022, 2 – entry into force 01.01.2023]

(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 in charge of the policy sector.

(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 investigations and application for right to make substantial modifications to investigations

[RT I, 22.12.2022, 2 – entry into force 01.01.2023]

(1) In order to conduct an investigation and make a substantial modification to the investigation, the sponsor must obtain the opinion of the ethics committee, taking account of the requirements specified in this Act and in Regulation (EU) 2017/745 or (EU) 2017/746 of the European Parliament and of the Council.

(2) The sponsor pays a fee to the ethics committee for giving an ethical opinion on the conduct of an investigation and making substantial modifications to an investigation.

(3) The fee specified in subsection 2 of this section is determined by the ethics committee on the basis of the following conditions:
1) the fee cannot be more than 3,000 euros;
2) in determining the size of the fee the ethics committee accounts for the costs related with the delivery of an opinion;
3) the size of the fee has been made public.

(4) The notification documents on making substantial modifications to investigations (hereinafter notification on modification to investigation) and an application for investigations may be submitted by the sponsor to the Health Board after the ethics committee has issued an opinion on the conduct of investigations or making substantial modifications to investigations.

(5) The sponsor is obliged to pay:
1) state fee according to the State Fees Act for review of the application for investigations;
2) the fee to the Health Board for professional assessment of the investigation pursuant to the regulation established under subsection 10 of this section before the submission on an application for investigations;
3) the fee to the Health Board for professional assessment of a substantial modification to investigations pursuant to the regulation established under subsection 10 of this section before the submission on an application for investigations.

(6) The maximum rate of the fee for professional assessment of an investigation specified in clause 2 of subsection 5 of this section is 3,000 euros and the maximum rate of the fee for professional assessment of making a substantial modification to investigations specified in clause 3 is 1,000 euros.

(7) The Health Board notifies of the decisions made on applications for investigations and notifications on modifications to investigations pursuant to the procedure provided for in Regulation (EU) 2017/745 or (EU) 2017/746 of the European Parliament and of the Council.

(8) The Health Board has the right to involve experts in the professional assessment of an investigation and in the assessment of compliance with the requirements for the conduct of an assessment. In the event an expert is involved in the assessment of an investigation the sponsor must pay the fee specified in clause 2 or 3 of subsection 5 of this section and the fee for an expert opinion according to the regulation established under subsection 10 of this section. The fee for an expert opinion per one assessment may not be more than 2,000 euros, unless agreed otherwise with the sponsor in writing.

(9) The persons assessing the investigation and verifying the compliance thereof with the requirements submit to the Health Board, by 31 May each year, the declaration of interests in which they confirm that they do not have a conflict of interests or any financial or other interests that may affect their impartiality.

(10) The size of the fee for expert opinion, professional assessment of application for investigations and the fee for professional assessment of a substantial modification to investigations and the payment procedure is established by a regulation of the minister in charge of the policy sector.
[RT I, 22.12.2022, 2 – entry into force 01.01.2023]

### § 22[1]. Requirements for the conduct of other clinical investigations of medical devices and applying for right to conduct such investigations

In the event of investigations specified in Article 82 of Regulation (EU) 2017/745 of the European Parliament and of the Council, the requirements provided for in subsections 2–7 of Article 62 and in Articles 63–66, 68–72, 75–77 and 80 are applied except for in those aspects concerning the submission of documents and exchange of information through the electronic system specified in Article 73 and the requirement to prepare a clinical assessment plan.
[RT I, 22.12.2022, 2 – entry into force 01.01.2023]

### § 22[2]. Requirements for conduct of other performance studies of *in vitro* diagnostic medical devices and for notification of such studies

(1) In the event of a study specified in Article 57 of Regulation (EU) 2017/746 of the European Parliament and of the Council which is not a study specified in subsection 1 or 2 of Article 58 and such study disturbs the integrity of the human, human embryo or foetus, subsection 4, points b–m and o of subsection 5 and subsections 6–8 of Article 58, Articles 59–62 and 64 and subsections 1, 4 and 6 of Article 68 are applied, except for in those aspects concerning the submission of documents and exchange of information through the electronic system specified in Article 69.

(2) The Health Board is informed of the conduct of a study specified in subsection 1 of this section at least ten days prior to the conduct of study.
[RT I, 22.12.2022, 2 – entry into force 01.01.2023]

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

[Repealed − RT I, 22.12.2022, 2 – entry into force 01.01.2023]

**§ 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 on medical devices**

[RT I, 22.12.2022, 2 – entry into force 01.01.2023]
A manufacturer or the authorised representative thereof is required to keep available for the Health Board the documents on medical devices as follows:
1) According to the provisions of point 8 of Chapter III of Annex IX, point 7 of Annex X, points 9 and 10.5 of Part A of Annex XI, points 17 and 18.4 of Part B of Annex XI and point 4 of Annex XIII to Regulation (EU) 2017/745 of the European Parliament and of the Council – for a period of at least 10 or 15 years;
2) According to the provisions of point 7 of Chapter III of Annex IX, point 6 of Annex X and points 6 of Annex XI of Regulation (EU) 2017/746 of the European Parliament and of the Council – for a period of at least ten years.
[RT I, 22.12.2022, 2 – entry into force 01.01.2023]

**§ 26. Notification of manufacture of medical devices manufactured within institution, making custom-made medical devices available on market, distribution of medical device or system and procedure pack of medical devices in Estonia for first time and transmission of data**

[RT I, 22.12.2022, 2 – entry into force 01.01.2023]

(1) The health care provider or research and development institution who manufactures medical devices within an institution (hereinafter the manufacturer within an institution) according to subsection 5 of Article 5 of Regulation (EU) 2017/745 or subsection 5 of Article 5 of Regulation (EU) 2017/746 of the European Parliament and of the Council, makes the list of such medical devices public on their website.

(2) A manufacturer within an institution submits to the Health Board, within 10 days after the manufacture of a medical device, the following information on a medical device manufactured in their institution:
1) documents specified in point f of subsection 5 of Article 5 for every medical device manufactured according to subsection 5 of Article 5 of Regulation (EU) 2017/745 of the European Parliament and of the Council;
2) documents specified in point g of subsection 5 of Article 5 for every medical device manufactured according to subsection 5 of Article 5 of Regulation (EU) 2017/746 of the European Parliament and of the Council.

(3) Every undertaking who makes a custom-made medical device available on the market notifies the Health Board of the intention to make such medical device available on the market at least 10 days prior to making such medical device available on the market.

(4) Every undertaking who distributes on the market of Estonia a system or procedure pack of medical devices according to Article 22 of Regulation (EU) 2017/745 of the European Parliament and of the Council or a class IIa, IIb or III medical device classified according to Regulation (EU) 2017/745 of the European Parliament and of the Council or 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, p 17–36) or Council Directive 93/42/EEC concerning medical devices (OJ L 169, 12.07.1993, p 1–43) or class B, C or D *in vitro* diagnostic medical devices classified according to Annex VIII of Regulation (EU) 2017/746 of the European Parliament and of the Council, shall notify the Health Board thereof within 10 days after distribution of the relevant medical device for the first time.

(5) The conditions and procedure for notification of making custom-made medical devices available on the market, of substantial modifications made to custom-made medical devices and distribution of medical devices in Estonia for the first time shall be established by a regulation of the minister in charge of the policy sector.
[RT I, 22.12.2022, 2 – entry into force 01.01.2023]

**§ 27. Registration of adverse incident and field safety notice**

[RT I, 22.12.2022, 2 – entry into force 01.01.2023]

(1) The Health Board registers the information of adverse incident notified thereto and notifies the person filing the information within 10 working days after the submission of information.

(2) The field safety notice is drawn in Estonian with regard to medical devices made available on the Estonian market. Initial field safety notice submitted for an urgent situation may also be in English.
[RT I, 22.12.2022, 2 – entry into force 01.01.2023]

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

[Repealed − RT I, 22.12.2022, 2 – entry into force 01.01.2023]

**§ 29. Medical Devices and Appliances Database**

[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 and analyse data concerning custom-made medical devices made available on the market and medical devices, systems and procedure packs of medical devices distributed in Estonia, the data concerning the adverse incidents and supervision proceedings connected therewith, investigations 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.
[RT I, 11.03.2023, 9 – entry into force 01.04.2023]

(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.
[RT I, 11.03.2023, 9 – entry into force 01.04.2023]

(3) The following data shall be processed in the Medical Devices and Appliances Database:
1) The data and documents related to making custom-made medical devices, system and procedure pack of medical devices available on the market and the data and documents related to the distribution of medical devices in Estonia;
[RT I, 22.12.2022, 2 – entry into force 01.01.2023]
2) the data and documents related to the registration and proceedings of averse incidents of medical devices;
3) the data and documents related to the clinical investigations and performance studies conducted only in Estonia or only in Estonia and another state besides the Member State of the European Union or the European Economic Area;
[RT I, 22.12.2022, 2 – entry into force 01.01.2023]
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 in charge of the policy sector.

(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**

[Repealed − RT I, 22.12.2022, 2 – entry into force 01.01.2023]

# Chapter 3
# PROFESSIONAL USE OF MEDICAL DEVICES

[RT I, 22.12.2022, 2 - entry into force 01.01.2023]

**§ 31. Requirements for professional use of medical devices**

[RT I, 22.12.2022, 2 – entry into force 01.01.2023]

(1) A medical device may be used upon the provision of health services in compliance with the intended purpose of the medical device and the instructions prescribed by the manufacturer, 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, 22.12.2022, 2 – entry into force 01.01.2023]

(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 professional user of a medical device 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, 22.12.2022, 2 – entry into force 01.01.2023]

(2) In cases where verifying the correct and safe performance of a medical device is required for putting the device into professional service, the professional user of a medical device must prepare a report on putting into professional service of the medical device.
[RT I, 22.12.2022, 2 – entry into force 01.01.2023]

# 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 safe use of the medical device for the intended purpose, the potential residual risks which may accompany the use of medical device and undesirable side effects and adverse events. Where appropriate the buyer's attention must be drawn to the restrictions, contraindications, precautionary measures and warnings related with the medical device.
[RT I, 22.12.2022, 2 – entry into force 01.01.2023]

(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 is drawn in English in one copy and issued on paper.
[RT I, 22.12.2022, 2 – entry into force 01.01.2023]

(3) Before the submission of an application, a manufacturer or their authorised representative applying for a certificate of free sale or a duplicate thereof is required to pay state fee according to the State Fees Act for the issue of a certificate of free sale or a duplicate thereof.
[RT I, 22.12.2022, 2 – entry into force 01.01.2023]

(4) A certificate of free sale is valid for two years after the issue thereof, except in case where the term of validity of a certificate of conformity of a medical device is shorter.
[RT I, 22.12.2022, 2 – entry into force 01.01.2023]

# Chapter 3[3]
# MEDICAL DEVICES MANUFACTURED WITHIN INSTITUTION

[RT I, 22.12.2022, 2 - entry into force 01.01.2023]

**§ 32[3]. Requirements for medical devices manufactured within institution**

(1) A manufacturer within an institution may manufacture medical devices within an institution only if the requirements set out in subsection 5 of Article 5 of Regulation (EU) 2017/745 or in subsection 5 of Article 5 of Regulation (EU) 2017/746 of the European Parliament and of the Council and in this Act are complied with.

(2) Point g of subsection 5 of Article 5 of Regulation (EU) 2017/746 of the European Parliament and of the Council shall also be applied to class B and C *in vitro* diagnostic medical devices.

(3) A manufacturer within an institution is not allowed to manufacture within an institution medical devices that contain nanomaterials, tissues and cells of animal origin that are non-viable or are rendered non-viable or their derivatives or that contain substance which when used separately, can be treated as a medicinal product for the purposes of the Medicinal Products Act.
[RT I, 22.12.2022, 2 – entry into force 01.01.2023]

# Chapter 3[4]
# IMPLANTABLE MEDICAL DEVICES

[RT I, 22.12.2022, 2 - entry into force 01.01.2023]

**§ 32[4]. Requirements for information related with implantable medical devices**

(1) The manufacturer of a medical device shall prepare the implant card delivered with an implantable medical device not specified in subsection 3 of Article 18 of Regulation (EU) 2017/745 of the European Parliament and of the Council in Estonian and provide the information required in points b–d of subsection 1 of Article 18 and the information necessary for a health care professional for filling in the implant card either in Estonian or translated into Estonian.

(2) A health care provider is required to, after implanting a patient with the implantable device, fill in the implant card set out in subsection 2 of Article 18 of Regulation (EU) 2017/745 of the European Parliament and of the Council and ensure the availability of information specified in subsection 1 of Article 18 to the patient.
[RT I, 22.12.2022, 2 – entry into force 01.01.2023]

# Chapter 3[5]
# ACTING AS CONFORMITY ASSESSMENT BODY

[RT I, 22.12.2022, 2 - entry into force 01.01.2023]

**§ 32[5]. Requirements for application by conformity assessment body for designation and language requirements for designation and notification procedure and exchange of information of notified body**

(1) The applicant submits the application by conformity assessment body for designation set out in Article 38 of Regulation (EU) 2017/745 or in Article 34 of Regulation (EU) 2017/746 of the European Parliament and of the Council (hereinafter application for designation) and the documents proving compliance with the requirements set out in Annex VII of Regulation (EU) 2017/745 or in Annex VII of Regulation (EU) 2017/746 of the European Parliament and of the Council to the Health Board.

(2) The application for designation and the documents related with the designation and notification procedure of a conformity assessment body (hereinafter designation and notification procedure) are either drawn in Estonian or English. The exchange of information related with the review of the application for designation, designation and notification procedure and periodic assessment and reassessment of a notified body shall be conducted either in Estonian or English.
[RT I, 22.12.2022, 2 – entry into force 01.01.2023]

**§ 32[6]. State fees for review of application for designation and notification of designation of conformity assessment body and for issue of activity licence**

(1) The applicant who submits an application for designation to the Health Board must pay state fee for review of the application for designation according to the State Fees Act.

(2) The applicant who has undergone an assessment according to Article 39 of Regulation (EU) 2017/745 or Article 35 of Regulation (EU) 2017/746 of the European Parliament and of the Council and who complies with Annex VII of Regulation (EU) 2017/745 or Annex VII of Regulation (EU) 2017/746 of the European Parliament and of the Council must, before the notification of designation as a conformity assessment body and receipt of an activity licence, pay state fee according to the State Fees Act.
[RT I, 22.12.2022, 2 – entry into force 01.01.2023]

**§ 32[7]. Fees for designation and assessment procedure and periodic assessment and reassessment of notified body**

(1) An applicant whose application for designation has been assessed to be complete must pay a fee to the Health Board for the designation and assessment procedure according to the regulation established under subsection 4 of this section.

(2) A notified body registered in Estonia shall pay to the Health Board a fee for periodic assessment of a notified body and a fee for reassessment of a notified body according to the regulation established under subsection 4 of this section.

(3) The maximum rate of the fee for designation and assessment procedure set out in subsection 1 of this section is 20,000 euros, the maximum rate of the fee for periodic assessment of a notified body set out in subsection 2 of this section is 10,000 euros and the maximum rate of the fee for reassessment of a notified body set out in subsection 2 is 18,000 euros.

(4) The size of the fee for designation and assessment procedure of a conformity assessment body, the periodic assessment of a notified body and reassessment of a notified body and the procedure of calculation and payment of the fee shall be established by a regulation of the minister in charge of the policy sector.
[RT I, 22.12.2022, 2 – entry into force 01.01.2023]

# 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 in this Act and legislation established on the basis thereof and in Regulation (EU) 2017/745 and Regulation (EL) 2017/746 of the European Parliament and of the Council;
[RT I, 22.12.2022, 2 – entry into force 01.01.2023]
3) over the notification and investigation of adverse incidents;
4) over the organisation of clinical investigations and performance studies;
[RT I, 22.12.2022, 2 – entry into force 01.01.2023]
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 for professional use of medical devices.
[RT I, 22.12.2022, 2 – entry into force 01.01.2023]
[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) [Repealed − RT I, 22.12.2022, 2 – entry into force 01.01.2023]

(3) [Repealed − RT I, 22.12.2022, 2 – entry into force 01.01.2023]

**§ 35. Inspection of conformity of medical devices with requirements**

(1) The Health Board is allowed to involve experts in the inspection of conformity of medical devices with the requirements and order assessment services for the inspection of conformity of medical devices or parts thereof with the requirements according to the regulation established under subsection 10 of § 22 of this Act.

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

(3) 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 proprietary damage. If the expert finds the medical device to be non-conforming, the costs of the assessment service shall be compensated to the Health Board by the relevant undertaking.
[RT I, 22.12.2022, 2 – entry into force 01.01.2023]

**§ 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 law enforcement agency may impose a coercive measure pursuant to the procedure provided for in the Substitutional Performance and Non-Compliance Levies Act. The maximum rate of non-compliance levy is 32,000 euros.
[RT I, 22.12.2022, 2 – entry into force 01.01.2023]

**§ 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 market, making available on market, manufacture within institution, putting into service, distribution and professional use of medical devices**

[RT I, 22.12.2022, 2 – entry into force 01.01.2023]

(1) Violation of the requirements for the placing on the market, making available on the market, manufacture within an institution, putting into service, distribution and professional use of medical devices is punishable by a fine of up to 200 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, 22.12.2022, 2 – entry into force 01.01.2023]

**§ 39[1]. Violation of requirements for conduct of clinical investigation of medical devices and performance study of *in vitro* diagnostic medical devices**

[RT I, 22.12.2022, 2 – entry into force 01.01.2023]

(1) Violation of the requirements for the conduct of clinical investigation of medical devices and performance study of *in vitro* medical devices is punishable by a fine of up to 200 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, 22.12.2022, 2 – entry into force 01.01.2023]

**§ 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]

**§ 41[2]. Implementation of obligations and requirements related with European database on medical devices**

Until the implementation date of the obligations set out in points d and e of subsection 3 of Article 122 of Regulation (EU) 2017/745 and in points a and f of subsection 3 of Article 113 of Regulation (EU) 2017/746 of the European Parliament and of the Council related with the European database on medical devices, the exchange of information with the Health Board and the transmission of data to the Health Board takes place according to the wording of the Medical Devices Act in force prior to entry into force of this wording.
[RT I, 22.12.2022, 2 – entry into force 01.01.2023]

**§ 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); 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, 22.12.2022, 2 – entry into force 01.01.2023]