Translation from Finnish

Legally binding only in Finnish and Swedish

Ministry of Social Affairs and Health, Finland

Medical Devices Act

(719/2021)

By decision of Parliament, the following is enacted:

Chapter 1

General provisions

Section 1

Scope of application

This Acts lays down provisions on the national implementation of 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, hereinafter the '*MD Regulation*', and of 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, hereinafter the '*IVD Regulation*'.

Sections 10, 11 and 31 to 33, section 34, subsections 1 and 5 to 8, chapters 5 and 6, section 56 and section 57, subsection 1, paragraphs 3 and 11, and subsections 2 and 3 of this Act shall also apply to medical devices fulfilling the requirements of Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, hereinafter the '*AIMD Directive*', or Council Directive 93/42/EEC on medical devices, hereinafter the '*MD Directive*', and to the obligations of operators who place and make such medical devices available on the market, market them and install and maintain them professionally and to the obligations of professional users regardless of when the device has been placed or made available on the market or put into service. In addition, section 57, subsection 1, paragraphs 1, 3 and 5 to 10, and subsections 2 and 3 shall apply to devices referred to in Article 120(3) and (4) of the MD Regulation and in Article 110(3) and (4) of the IVD Regulation.

Sections 31 to 33, section 34, subsections 1 and 5 to 8, sections 48 and 49, chapter 6 and section 56 of this Act shall also apply to in vitro diagnostic medical devices falling within the scope of the Act on Certain Medical Devices Specified in EU Directives (629/2010).

The provisions of this Act governing medical devices shall also apply to in vitro diagnostic medical devices, unless otherwise provided below.

Government proposal 67/2021

Memorandum of the Social Affairs and Health Committee 13/2021

Reply by Parliament 87/2021

Regulation of the European Parliament and Council (EU) No 745/2017 (32017R0745); OJ L 117, 5.5.2017, p. 1, Regulation (EU) No 746/2017 of the European Parliament and Council (32017R0746); OJ L 117, 5.5.2017, p. 176 Regulation (EU) No 1020/2019 of the European Parliament and Council (32019R1020); OJ L 169, 25.6.2019, p. 1

The provisions of this Act governing medical devices shall also apply to accessories for a medical device, unless otherwise provided in the MD Regulation, the IVD Regulation or in the Act on Certain Medical Devices Specified in EU Directives.

The provisions of this Act governing medical devices shall also apply to products referred to in Annex XVI of the MD Regulation which fall into the scope of the MD Regulation, unless otherwise provided in the MD Regulation.

Section 2

Relationship to other legislation

Further to the provisions of the MD Regulation and the IVD Regulation, the Radiation Act (859/2018) shall apply to radiation safety in the use of devices emitting ionising radiation, radioactive substances and medical devices related to radiation safety. The Radiation Act shall also apply to the radiation safety of medical devices emitting non-ionising radiation or operating according to similar principles in so far as they expose the population to radiation.

Provisions on devices falling within the scope of Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices, hereinafter the '*IVD Directive*', are laid down in the Act on Certain Medical Devices Specified in EU Directives. The above-mentioned Act also provides for the requirements devices pursuant to the AIMD Directive and the MD Directive must fulfil in order to be placeable on the market under Article 120(3) of the MD Regulation.

Articles 120, 122 and 123 of the MD Regulation and Articles 110, 112 and 113 of the IVD Regulation provide for when the AIMD Directive, the MD Directive, the IVD Directive or the MD Regulation or the IVD Regulation is to be applied and lay down transitional provisions.

Chapter 2

Economic operators, certain other operators and notified bodies

Section 3

Qualifications of persons responsible for regulatory compliance

The Finnish Medicines Agency (Fimea) may issue regulations on national requirements for the qualifications of a person responsible for regulatory compliance referred to in Article 15(1) and (6) of the MD Regulation and in Article 15(1) and (6) of the IVD Regulation.

Section 4

Prohibition to reprocess and reuse single-use devices

Single-use devices may not be reprocessed or reused in Finland.

Section 5

Requirements for the language to be used

The information and documents referred to in Article 10(11) of the MD Regulation and in Article 10(10) of the IVD Regulation must be in Finnish, Swedish or English, unless the information is provided in the form of internationally recognised symbols. Information necessary for the safe use of a device must, however, be available in Finnish and in Swedish. The manufacturer must determine, based on a risk assessment, which information is necessary for safe use. If a device is intended for use by patients or other consumers, instructions for use and other information necessary for safe use must be available in Finnish and in Swedish. The instructions for use and labels of single-use devices referred to in the MD Regulation must be either in Finnish or in Swedish or in both languages, depending on the user's needs.

The information referred to in Article 18(1)(1) of the MD Regulation must be in Finnish, Swedish and English.

The documents referred to in Article 19(1), in subparagraph 1 of Article 41 and in Article 56(1) of the MD Regulation as well as in Article 17(1), in subparagraph 1 of Article 37 and in Article 51(1) of the IVD Regulation must be drafted in Finnish, Swedish or English. The documents referred to

in Article 52(12) of the MD Regulation and in Article 48(12) of the IVD Regulation must be available in Finnish, Swedish or English.

The Finnish Medicines Agency may, when required by safety, order the manufacturer and the authorised representative to submit, free of charge, the information and documents referred to in Article 10(14) and Article 11(3)(2)(d) of the MD Regulation and in Article 10(13) and Article 11(3)(2)(d) of the IVD Regulation or their parts defined by the Agency in Finnish or in Swedish.

The notices referred to in Article 89(8) of the MD Regulation and in Article 84(8) of the IVD Regulation must be drafted in the languages necessary for safety. The Finnish Medicines Agency may order the manufacturer to draft a notice free of charge in a certain language or languages.

The Finnish Medicines Agency may issue further regulations on the language requirements of the information and documents referred to in this section and on the procedures for fulfilling them.

Section 6

Custom-made devices

A written prescription required for manufacturing a custom-made device referred to in the MD Regulation may be issued only by a health care professional referred to in the Health Care Professionals Act (559/1994) who has the knowledge and professional skills required for issuing the prescription, considering the purpose of the device.

The Finnish Medicines Agency may issue regulations on the obligation of the manufacturer of a custom-made device to draft a list of the devices it has manufactured and submit it to the Agency.

Section 7

Obligation of manufacturers and authorised representatives to ensure storage of documents

Manufacturers and authorised representatives shall ensure that regardless of a bankruptcy or cease of business activity for other reason, the Finnish Medicines Agency has the following available:

1) the documents referred to in Section 7 of Annex IX of the MD Regulation;

2) the documents referred to in Section 7 of Annex X of the MD Regulation;

3) the documents referred to in Sections 10(5) and 18(4) of Annex XI of the MD Regulation;

4) the information referred to in Section 4 of Annex XIII of the MD Regulation;

5) the documents referred to in Section 6 of Annex IX of the IVD Regulation;

6) the documents referred to in Section 6 of Annex X of the IVD Regulation;

7) the documents referred to in Section 6 of Annex XI of the IVD Regulation.

The documents referred to in subsection 1 above shall be kept available to the Finnish Medicines Agency for the period provided in the Regulations mentioned in the subsection.

The Finnish Medicines Agency may issue regulations on the principles and procedures to be applied in keeping the documents referred to in subsection 1.

Section 8

Obligations of importers, authorised representatives and distributors

The provisions of the MD Regulation and the IVD Regulation on the obligations of importers and authorised representatives also apply to the importers and authorised representatives when they place on the market a medical device that fulfils the requirements of the AIMD Directive, the MD Directive or the IVD Directive under Article 120(3) of the MD Regulation or Article 110(3) of the IVD Regulation.

The provisions on the distributor's obligations laid down in the MD Regulation and the IVD Regulation also apply when the distributor places on the market a medical device that fulfils the requirements of the AIMD, MD or IVD Directives under Article 120(4) of the MD Regulation or Article 110(4) of the IVD Regulation.

Section 9

Requirements of good administrative practice and public liability in notified bodies

Provisions on the principles of good administrative practice which a notified body must apply when carrying out public administrative tasks are laid down in the Administrative Procedure Act (434/2003), in the Language Act (423/2003), in the Act on Electronic Services and Communication in the Public Sector (13/2003) and in the Act on the Openness of Government Activities (621/1999).

A person employed by a notified body or by its subcontractor shall be subject to the provisions on criminal official liability when he or she carries out tasks referred to in the MD Regulation or the IVD Regulation. Provisions on the liability for damages are laid down in the Tort Liability Act (412/1974).

Section 10

Marketing

Provisions on the labelling, instructions for use, making available and putting into service of devices and on claims presented in their advertising are laid down in Article 7 of the MD Regulation and in Article 7 of the IVD Regulation. The provisions on prohibited claims laid down in the above-mentioned Articles apply to any kind of marketing of the device.

Marketing shall indicate the manufacturer of the device and the product or trade name given by the manufacturer upon the registration of the device.

Marketing shall indicate that the device is a CE-marked medical device. If a certificate by a notified body is required for the device, marketing shall further state the number of the notified body that issued the certificate.

A device which is not a medical device may not be claimed to be a medical device in marketing.

Notwithstanding the provisions of subsection 4, it is allowed to market a device which is to be placed on the market as a medical device but whose conformity has not yet been proven pursuant to the MD Regulation or the IVD Regulation, as well as a device for which the Finnish Medicines Agency has granted an exception order under section 58 of this Act if marketing highlights that the device is not a CE-marked medical device.

Marketing targeted at consumers is also governed by the Consumer Protection Act (38/1978).

The Finnish Medicines Agency may issue regulations on procedures to be applied in marketing.

Section 11

Professional installation and maintenance

A person who professionally installs or maintains medical devices shall follow the information and instructions provided by the manufacturer on the transport, storage, installation, maintenance, data security, updates and other handling of the device.

The person referred to in subsection 1 above shall ensure that when he or she dispenses a medical device to the end user, the device is in a condition in which the manufacturer has intended it to be used. The device must be, where applicable, maintained appropriately before it is dispensed.

The person referred to in subsection 1 above shall inform the manufacturer, authorised representative, importer or the distributor of any serious incident which has been brought to his or

her attention and which has been found or is suspected to have been caused by a fault or defect in the device.

Chapter 3

Clinical investigations and performance studies of in vitro diagnostic devices

Section 12

Competence requirements

An investigator referred to in Article 2(54) of the MD Regulation and Article 2(48) of the IVD Regulation shall have an appropriate professional and scientific competence.

The medical care provided to the subjects is the responsibility of an appropriately qualified medical doctor or, in the case of an odontological investigation, an appropriately qualified dental practitioner.

A member of the investigating team referred to in Article 63(2)(c) of the MD Regulation and in Article 59(2)(c) of the IVD Regulation, who gives information in a prior interview for obtaining an informed consent, shall have adequate information on the investigation or study concerned as well as on the regulation on informed consent.

Section 13

Legal representatives and contact persons of sponsors

If a clinical device investigation or a performance study is to be carried out solely in the Finnish territory or solely in the territory of Finland and a state not belonging to the European Union or the European Economic Area and the sponsor of the investigation or study is not established in a European Union Member State, the sponsor must designate a legal representative referred to in Article 62(2) of the MD Regulation or in Article 58(4) of the IVD Regulation. However, the Finnish Medicines Agency may, upon the sponsor's application, grant an authorisation to the fact that the investigation or study has, in lieu of a legal representative, a contact person referred to in the above-mentioned paragraphs.

A sponsor who in accordance with the provisions of subsection 1 wants to designate a contact person in lieu of a legal representative may not file an application for the investigation or study in the electronic system referred to in Article 73 of the MD Regulation and in Article 69 of the IVD Regulation until a positive decision by the Finnish Medicines Agency on the authorisation to designate a contact person is legally valid. If the electronic system referred to above is not in operation, an application may not be filed with an ethics committee and the Finnish Medicines

Agency until after a positive decision by the Finnish Medicines Agency on the authorisation to designate a contact person is legally valid.

The Finnish Medicines Agency grants the authorisation referred to in subsection 1 if it considers that the authorisation does not pose significant risks to the protection of subjects and their access to justice or to the fulfilment of other requirements of the MD Regulation or the IVD Regulation.

Further provisions on the information required in the application and on the application procedure may be issued by a decree of the Ministry of Social Affairs and Health.

Section 14

Insurance or other security

The sponsor shall ensure that there is a valid insurance for compensating for injuries caused to the subjects or other appropriate security for covering the sponsor's and the investigator's liability.

Section 15

Language of application documents

Finnish, Swedish or English may be used as the language in application documents relating to performance studies under Chapter II of Annex XV of the MD Regulation and Chapter I of Annex XIV of the IVD Regulation. The documents pursuant to Chapter II, Sections 1(11), 3(13) and 4(4) of Annex XV of the MD Regulation and Section 2(3)(2)(u) of Annex XIII and Chapter I, Sections 1(11) and 4(4) of Annex XIV of the IVD Regulation shall, however, be submitted to the electronic system referred to in Article 73 of the MD Regulation and in Article 69 of the IVD Regulation in Finnish or in Swedish.

Section 16

Certain investigations referred to in the MD Regulation

An investigation referred to in Article 82 of the MD Regulation shall be governed by the provisions of Article 62(2) and (3), Article 62(4)(b) to (l), Article 62(5) to (7), Articles 63 to 68, Article 71(3) and Article 72(1) to (4) and (6) of the MD Regulation as well as by sections 14 to 20, section 21, subsections 7 to 11 and sections 25 to 28 of this Act. In addition, Chapter I of Annex XV of the MD Regulation shall be applied with the exception of the reference to Article 62(1) in Section 2(1) and the obligation laid down in Section 2(4) to carry out the investigation in accordance with a plan for clinical evaluation referred to in Part A of Annex XIV. In addition, Chapter III, Sections 2, 3(1) and 5 of Annex XV shall be applied.

The sponsor or investigator shall draft an appropriate report on the investigation referred to in Article 82 of the MD Regulation within a year after the investigation was completed. The Finnish Medicines Agency may issue regulations on the content and drafting of the report if an investigation is suspended or terminated early.

An investigation referred to in Article 82 of the MD Regulation is also subject to Article 77(1) to (4) and Article 80(1) and (2) of the Regulation, except that the notices and information referred to in the said Articles shall be submitted to the Finnish Medicines Agency. If a clinical investigation is also carried out outside the European Union or the European Economic Area, the sponsor shall submit, without delay, information to the Finnish Medicines Agency on the death of a subject or on a serious injury to a subject in connection with the investigation and, every three months, a summary of incidents under Article 80(2) which have occurred outside the European Union or the European Economic Area.

Section 17

Certain performance studies under the IVD Regulation

If a performance study is not a study referred to in Article 58(1) of the IVD Regulation or a study referred to in paragraph 2 of the said Article which is subject to the same provisions as studies under paragraph 1 but is a study referred to in Article 57 which intervenes in the integrity of a human being, human embryo or a foetus, it shall be subject to Article 58(4), Article 58(5)(b) to (m) and (o) and Article 58(6) to (8), Articles 59 to 64, Article 68(1) to (4) and (6) as well as to sections 12 to 14, section 18, subsections 1 to 3 and 5, section 19, section 20, subsections 2 to 4 and sections 25 to 28 of this Act.

Before starting a study referred to in subsection 1, it is necessary to obtain a favourable opinion on the study by the competent ethics committee referred to in section 18.

Studies involving companion diagnostics referred to in Article 58(2) of the IVD Regulation which use only left-over samples and other studies pursuant to Article 57 of the IVD Regulation not referred to in subsection 1 shall be subject to the requirements concerning studies and the processing of personal data laid down in Article 68(3) and (4).

Section 18

Competent ethics committee

The sponsor shall submit application documents concerning an investigation or study to a regional ethics committee referred to in section 16 of the Medical Research Act (488/1999), which will carry out an ethical review of the clinical investigation or performance study.

The investigation project will be evaluated in advance by the regional ethics committee in the region of which the investigation or study will be principally carried out or, where such principal performance region does not exist, by the regional ethics committee selected by the sponsor in the region of which the investigation or study is performed. The committee will also give an opinion on the investigation project.

If an investigation or study is carried out by combining it with clinical trials on medicinal products, the ethical review of the investigation or study is carried out by the National Committee on Medical Research Ethics. It is possible to derogate from the provisions of section 21, subsection 1 and section 22, subsection 1 in such an investigation or study if the assessment of the application for clinical trials on medicinal products requires this.

If a substantial modification referred to in Article 75 of the MD Regulation or in Article 71 of the IVD Regulation is intended to be introduced into the investigation plan or documents drafted on the basis of it or into procedures, the ethics committee that issued an opinion on the investigation or study shall issue an opinion on the modification. In the case of investigations or studies referred to in subsection 3, the opinion shall be issued by the National Committee on Medical Research Ethics.

Further provisions on the ethical review in investigations or studies referred to in subsection 3 may be issued by government decree. Provisions on the documents to be submitted to the ethics committee and on their language requirements may be laid down by a decree of the Ministry of Social Affairs and Health.

Section 19

Ethical review of investigations or studies

A regional ethics committee and, in the cases referred to in section 18, subsection 3, the National Committee on Medical Research shall review an investigation plan and other documents submitted to it and issue an opinion on the investigation or study. It shall particularly take the following issues into consideration:

1) compliance with the requirements laid down in section 4 of the Medical Research Act;

2) necessity and relevance of the investigation or study;

3) appropriateness of the investigation or study and its planning, considering statistical considerations and the design and methodology of the investigation or study;

4) appropriateness of the assessment of the benefits and risks of the investigation or study and validity of the related conclusions;

5) compliance with the requirements for informed consent, appropriateness of the material provided for informed consent and the procedure to be applied to obtain an informed consent;

6) justification for the fact that the investigation or study is directed at subjects referred to in Article 64 or 65 of the MD Regulation, in Article 60 or 61 of the IVD Regulation or in section 25 or 26 of this Act;

7) justification for the fact that the investigation or study is directed at subjects referred to in Article 66 or 68 of the MD Regulation, in Article 62 or 64 of the IVD Regulation or in section 27 of this Act or at subjects in another special situation;

8) detailed procedures for recruiting subjects;

9) amount of the fee or compensation paid to the investigators and the amount of compensation paid to the subject and his or her close relatives or the grounds for determining the compensation, and any related procedures;

10) competence of the investigator and other persons centrally involved in carrying out the investigation or study;

11) appropriateness of the facilities and equipment used in the investigation or study;

12) grounds for compensating any injury resulting from the investigation or study and insurances and other arrangements for covering a compensation for an injury or death.

An expert in paediatrics shall be represented or consulted at the regional ethics committee and the National Committee on Medical Research when it is dealing with an investigation or study to be performed on a minor as well as an expert familiar with the disease or injury concerned when the committee deals with an investigation or study to be carried out on a subject referred to in section 25.

The opinion of the regional ethics committee and the National Committee on Medical Research shall include a substantiated opinion on whether the investigation or study is ethically acceptable.

Section 20

Application of the Medical Research Act

Regardless of whether a clinical investigation referred to in the MD Regulation, a performance study referred to in Article 58(1) of the IVD Regulation or a study referred to in Article 58(2) governed by the same provisions as studies subject to Article 58(1) constitutes medical research referred to in the Medical Research Act, the investigation or study and its ethical review shall be subject to section 3, subsections 1, 2 and 4, section 4, chapter 3, section 16, section 17, subsection 3, section 18, subsections 1 to 3 and sections 19 and 23 of the Medical Research Act.

If the investigation or study is a study pursuant to section 17, subsection 1, it shall be subject to subsection 1 of this section. In addition, if the sponsor intends to introduce modifications into the study which probably have a substantial effect on the safety, health or rights of the subjects or on the reliability or robustness of the clinical data generated in the study, it shall further be subject to the procedure laid down in section 3, subsection 3 of the Medical Research Act.

Regardless of whether a clinical investigation referred to in the MD Regulation or a performance study referred to in the IVD Regulation constitutes medical research pursuant to the Medical Research Act, personal data may be processed in the investigation or study in accordance with the provisions laid down on the processing of personal data in the Medical Research Act.

The Medical Research Act does not apply to a clinical investigation referred to in the MD Regulation and to a performance study referred to in the IVD Regulation except for as provided in this section.

Section 21

Assessment of clinical investigations pursuant to the MD Regulation by authorities

A sponsor may not submit an application for a clinical investigation and a notice of a substantial modification to an investigation to the electronic system referred to in Article 73 of the MD Regulation until a regional ethics committee has given an opinion on the investigation.

The Finnish Medicines Agency will assess the application for an investigation and the notice of a substantial modification, the appropriateness of the associated documents and the issues referred to in Article 71(3) of the MD Regulation. The Agency may also assess issues referred to in section 19, subsection 1 of this Act.

The Finnish Medicines Agency will make a decision on authorisation pursuant to Article 70(7)(b) of the MD Regulation.

The Finnish Medicines Agency will make a decision on authorisation for investigations concerning devices of classes IIa and IIb referred to in Article 70(7)(a) of the MD Regulation. The Agency

shall inform the sponsor of its authorisation decision within 45 days from the validation date referred to in paragraph 5 of the Article. The Agency may extend the period by 20 days for the purpose of consulting with experts.

An investigation concerning devices of class I referred to in Article 70(7)(a) of the MD Regulation may be started pursuant to the subparagraph, unless the Finnish Medicines Agency announces at the latest on the validation date referred to in Article 70(5) that the investigation may not be started. The Agency shall make a decision on the matter if it prohibits the investigation.

If the assessment by the Finnish Medicines Agency on the notice of a substantial notification pursuant to Article 75 is negative, it will make a decision on the matter.

In derogation from the provisions of subsection 1, the sponsor shall submit an application for a clinical device investigation or a notice of a substantial modification to the Finnish Medicines Agency in connection with investigations pursuant to Article 82 of the MD Regulation. The application or notice may not be submitted to the Agency until a regional ethics committee has given an opinion on the investigation or substantial modification. The Finnish Medicines Agency may request the sponsor to provide further clarifications or supplement the application or notice. A time limit shall be set for the request.

In a situation provided in subsection 7, the Finnish Medicines Agency shall make a decision on investigations referred to in subsection 4 at the latest within 65 days from the filing of the application or receipt of further clarifications or supplements whether it will authorise the new investigation. In a situation provided in subsection 7, an investigation referred to in subsection 5 may be started within 25 days from the filing of the application or, if further clarifications have been submitted, within 5 days after their sending if the Agency does not announce within 5 days that the investigation may not be started. The Agency shall prohibit starting the investigation if it does not fulfil the requirements laid down for investigations in section 1, subsection 1. The Agency shall make a decision on the matter if it prohibits the investigation.

A substantial modification may be implemented if the Finnish Medicines Agency has not prohibited its implementation within 45 days from the filing of the notice or, if the Agency has requested further clarifications or supplements, within 10 days after their submission if the Agency has not prohibited the implementation of the substantial modification. If the Agency prohibits the implementation of the substantial modification, it will make a decision on the matter.

When making a decision referred to in subsections 3 to 6 and 8 on the acceptability of an investigation, the Finnish Medicines Agency shall consider the opinion by a regional ethics

committee. A negative opinion by the committee or an opinion requiring the fulfilment of detailed special conditions as a condition for acceptability is binding on the Agency.

The Finnish Medicines Agency will give regulations on documents which shall be submitted to the Finnish Medicines Agency for the assessment of an investigation pursuant to Article 82 of the MD Regulation.

Section 22

Assessment of performance studies pursuant to the IVD Regulation by authorities

A sponsor may not submit an application for a performance study and a notice of a substantial modification to a study to the electronic system referred to in Article 69 of the IVD Regulation until a regional ethics committee has given an opinion on the study.

The Finnish Medicines Agency will assess the application for a study and the appropriateness of the associated documents as well as the issues referred to in Article 67(3) of the IVD Regulation. The Agency may also assess issues referred to in section 19, subsection 1 of this Act.

The Finnish Medicines Agency will make a decision on authorisation pursuant to Article 66(7)(b) of the IVD Regulation.

A study referred to in Article 66(7)(a) of the IVD Regulation may be started pursuant to the subparagraph unless the Finnish Medicines Agency announces at the latest on the validation date referred to in Article 66(5) that the study may not be started. The Agency shall make a decision on the matter if it prohibits the study.

If the assessment by the Finnish Medicines Agency on the notice of a substantial modification referred to in Article 71 is negative, it will make a decision on the matter.

When making a decision referred to in subsections 3 to 5 on the acceptability of a study, the Finnish Medicines Agency shall consider the opinion by a regional ethics committee. A negative opinion by the committee or an opinion requiring the fulfilment of detailed special conditions as a condition for acceptability is binding on the Agency.

Section 23

Reporting of certain studies falling within the scope of the IVD Regulation

A sponsor shall notify the Finnish Medicines Agency of performance studies involving companion diagnostics referred to in Article 58(2) of the IVD Regulation which use only samples not obtained

from the study subjects or where such a study is carried out using samples obtained under the Biobank Act (688/2012) at the latest 10 days before starting the study.

The Finnish Medicines Agency may issue regulations on the content of the notice referred to in this section.

Section 24

Coordinated assessment procedure

The Finnish Medicines Agency and the regional ethics committee may, before undertaking a coordinated assessment procedure laid down in Article 78 of the MD Regulation and in Article 74 of the IVD Regulation, assess the selected investigation or study in accordance with the procedure provided in the Articles. The assessment may derogate from the provisions of sections 21 and 22 of this Act in so far as this is necessary for compliance with the coordinated assessment procedure.

The requirement for applying the procedure under subsection 1 is that the sponsor has given its consent to this to the Finnish Medicines Agency and the regional ethics committee.

Section 25

Subjects with reduced self-determination

A subject referred to in Article 64 of the MD Regulation and in Article 60 of the IVD Regulation is a person who because of a disease, injury or other similar reason not associated with age is not capable of understanding the information provided in accordance with Article 63 of the MD Regulation or Article 59 of the IVD Regulation in order to independently give an informed consent to participation in an investigation or study on the basis of the information.

The subject's legally designated representative, who is authorised to give an informed consent on behalf of the subject referred to in subsection 1, is the person's legal representative or, if there is no legal representative, his or her close relative or other close person.

Section 26

Minor subjects

A person under 18 years of age may be a subject only if the provisions of the MD Regulation or the IVD Regulation on minors and the provisions of this Act are applied to him or her in the study or investigation.

The legally designated representative of a person under 18 years of age, who is authorised to give an informed consent on behalf of the minor subject, is his or her guardian or other legal representative.

If the subject has, however, reached the age of 15, he or she may himself or herself give an informed consent to an investigation or study in respect of which there are scientific grounds for expecting that participation in the investigation or study will produce direct benefits for the minor subject, unless he or she is, considering his or her age or development level, the nature of the disease or the quality of the investigation or study, unable to understand the relevance of the investigation or study or of a research measure. The guardian or legal representative shall also in this case be informed of the matter.

If a subject under 18 years of age, who may not be a subject without a consent from his or her guardian or other legal representative, is capable of forming an opinion and assessing the information given to him or her on the investigation or study, a written consent is also required from such subject.

Section 27

Prisoners or forensic psychiatric patients as subjects

In addition to the provisions laid down on informed consent in the MD Regulation, the IVD Regulation and in this Act, a prisoner referred to in the Imprisonment Act (767/2005), a remand prisoner referred to in the Remand Imprisonment Act (768/2005), a person in treatment or care under chapter 3 or 4 of the Mental Health Act (1116/1990) or a person deprived of his or her liberty under another Act may be a subject only if there are scientific grounds for expecting that the investigation or study will produce a direct benefit for his or her health, for the health of his or her relative or for the health of his or her other reference group referred to in this section.

Section 28

Compensation for subjects

Provisions on the prohibition to offer incentives or financial inducements to subjects referred to in section 25 or 26 or to their legally designated representatives or to pregnant or breastfeeding women as subjects and on the possibility of paying compensation are laid down in Article 64(1)(d), in subparagraph d of Article 65 and in subparagraph c of Article 66 of the MD Regulation and in Article 60(1)(d), Article 61(1)(d) and in subparagraph d of Article 62 of the IVD Regulation. Other subjects may be paid, in addition to compensation for expenses and loss of earnings directly

related to the participation in the investigation or study, a reasonable compensation for other harm.

Further provisions on the grounds for and amounts of compensation may be issued by government decree.

Section 29

Reporting obligation of investigators

The investigator shall inform the sponsor without delay of incidents and other adverse events referred to in Article 80(2) of the MD Regulation and in Article 76(2) of the IVD Regulation.

Section 30

Obligation to keep documents on investigation or study

The sponsor or its legal representative or contact person shall ensure that regardless of a bankruptcy or cease of business activity for another reason, the documents pursuant to Chapter III, Section 3 of Annex XV of the MD Regulation and the documents pursuant to Chapter II, Section 3 of Annex XVI of the IVD Regulation are available to the Finnish Medicines Agency for the period laid down in the above-mentioned provisions.

The Finnish Medicines Agency may issue regulations on the principles and procedures to be applied in keeping the documents referred to in subsection 1.

Chapter 4

Professional user and device manufacture by health institutions

Section 31

Definitions

'*Professional user*' means:

1) a health care unit referred to in section 2, subsection 4 of the Act on the Status and Rights of Patients (785/1992), a blood service facility referred to in section 2, subsection 2 of the Blood Service Act (197/2005), a tissue facility referred to in section 1a, subsection 4 of the Act on the Medical Use of Human Organs, Tissues and Cells (101/2001), a special care unit referred to in section 9 of the Act on Special Care Services for People with Intellectual Disabilities (519/1977) and such public and private establishments that provide social welfare services referred to in

section 14 of the Social Welfare Act (1301/2014) and use medical devices in their activities or dispense them to patients or social welfare clients;

2) a health care professional referred to in the Health Care Professionals Act who uses a medical device in the context of professional activities or dispenses them to patients;

3) a natural or legal person other than those referred to in paragraph 1 or 2 whose business or professional activities aim at the following:

a) diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of or compensation for disease, injury or disability;

b) investigation, replacement or modification of the anatomy or of a physiological or pathological process or state; or

c) providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations;

4) a natural or legal person other than those referred to in paragraphs 1 to 3 who uses medical devices in instruction for activities referred to in paragraph 3;

5) a natural or legal person who in the context of professional or business activities uses a product referred to in Annex XVI of the MD Regulation.

'*Health institution*' means an organisation referred to in Article 2(36) of the MD Regulation and in Article 2(29) of the IVD Regulation whose main task is to treat patients or promote public health.

Section 32

General requirements for professional use

A professional user shall have a responsible person who is responsible for ensuring that the user's activities comply with the requirements laid down in this Act or in another Act.

A professional user shall ensure that

1) a person using a medical device has the training and experience required by its safe use;

2) devices used for medical purposes as well as products referred to in Annex XVI of the MD Regulation shall be CE-marked medical devices, custom-made devices, devices manufactured in accordance with provisions on self-manufacture or devices for which an authority has granted an authorisation for placing them on the market or putting them into service even though their

conformity has not been assessed in accordance with the provisions of EU Regulations or national laws.

3) the device has or is accompanied with labelling and instructions for use required for safe use;

4) the device is used for the purpose stated by the manufacturer and in accordance with the manufacturer's instructions;

5) the device is adjusted, maintained and serviced according to the manufacturer's instructions and otherwise appropriately;

6) the place of use is suitable for safe use of the device;

7) other medical devices, components and structures, accessories, software and other systems and objects connected to the device or in its immediate vicinity do not compromise the device's performance or the health of the patient, user or other person; and

8) the device is installed, serviced and repaired only by a person with a required proficiency and expertise.

A professional user shall be able to prove that he or she complies with the obligations under subsections 1 and 2 in his or her activities.

Section 33

Reporting serious incidents

A professional user shall inform the Finnish Medicines Agency as well as the manufacturer, authorised representative, importer or distributor of serious incidents that have or could have endangered the health of a patient, user or other person and result from the following issues associated with the medical device:

1) features;

2) undesirable side effects;

3) deviation from performance or an error;

4) inadequate labelling;

5) inadequate or incorrect instructions for use; or

6) other use-related reason not mentioned in paragraphs 1 to 5.

The Finnish Medicines Agency may issue regulations on how serious incidents shall be reported and which information shall be reported.

Section 34

Monitoring system

Health care units and other professional users who are legal persons or use a medical device as a self-employed person shall have a monitoring system for ensuring the safety of devices and their use. The following shall be entered into the monitoring system:

1) information required for the traceability of the devices used or dispensed by the unit or otherwise in its possession as well on devices installed in patients;

2) information on serious incidents that have arisen during the use of the device.

In the context of the monitoring system under subsection 1, a UDI referred to in Article 27 of the MD Regulation shall be stored and kept in respect of implementable devices classified into class III in accordance with Article 51(1) of the Regulation which have been supplied to a professional user or which the user has implanted in a patient or dispensed otherwise. The UDI may be stored and kept by electronic and other means.

Provisions on the obligation of a health institution to store the UDI referred to in subsection 2 by electronic or other means are laid down in Article 27(9) of the MD Regulation.

Health institutions and professional users may also store and keep the UDI of other medical devices and in vitro diagnostic medical devices than those referred to in subsection 2 which have been supplied to them or which they have dispensed.

The patient's name, personal identity code or a similar code and necessary contact details may be stored in the monitoring system referred to in subsection 2 above. In addition, the information on the patient's health and treatment that is necessary for the device's traceability may be stored in the monitoring system. Stored personal data shall be kept confidential. The information shall be kept for the period required by the safety of the medical device.

If the information referred to in subsections 1 and 5 is entered and kept as part of patient documents referred to in the Act on the Status and Rights of Patients, the information shall be subject to the provisions governing patient documents.

The information may not be disclosed for marketing purposes.

The Finnish Medicines Agency may issue further regulations on the information to be entered into the monitoring system.

Section 35

Self-manufacture of devices by health institutions

Health institutions may engage in self-manufacture of devices in compliance with Article 5(5) of the MD Regulation and Article 5(5) of the IVD Regulation. The self-manufacture of devices by health institutions may not involve reprocessing of single-use devices referred to in Article 17 of the MD Regulation or manufacture of devices whose use involves a particular risk.

Article 5(5)(g) of the IVD Regulation also applies to devices belonging to classes A, B and C under Article 47(1) of the Regulation.

If a health institution is engaged in self-manufacture of devices, it shall have a person responsible for manufacture. The responsible person shall approve the putting into service of a device manufactured by the institution after having ensured that the requirements of Article 5(5) of the MD Regulation and Article 5(5) of the IVD Regulation have been complied with in the manufacture. The health institution shall draft a declaration approved by the responsible person through his or her signature, stating that the above-mentioned requirements have been complied with in the manufacture of the device. The declaration shall be kept available to the Finnish Medicines Agency for five years following the putting into service of the device.

Further provisions on devices that may not be manufactured by health institutions because of a particular risk involved may be issued by a decree of the Ministry of Social Affairs and Health. The Finnish Medicines Agency may issue regulations on information that shall be submitted to it on the manufacture and use of devices referred to in subsection 1.

Section 36

Implant card and information to be given to patients on implanted devices

When a medical device has been implanted in a patient, the health institution and other professional user shall supplement the implant card referred to in Article 18(2) of the MD Regulation with health care-related information. They must further ensure that the information referred to in paragraph 1 of the Article is available to the patient.

The Finnish Medicines Agency may issue regulations on the obligations of health institutions and professional users with regard to the implant card as well as on how the information on the implant shall be made available to the patient.

Chapter 5

Supervision and coercive administrative measures

Section 37

Competent authority

The Finnish Medicines Agency shall be responsible for the general steering and supervision of the activities pursuant to this Act. The Agency shall supervise and promote the safety and conformity of medical devices and their use.

The Finnish Medicines Agency is the competent authority for medical devices referred to in the MD Regulation and the competent authority for in vitro diagnostic medical devices referred to in the IVD Regulation as well as the authority responsible for notified bodies referred to in the Regulations. The Agency is also competent to carry out the tasks of a Member State laid down in the MD Regulation and in the IVD Regulation and exercise the competences of a Member State laid down in the Regulations, unless otherwise provided in this or another Act.

The Finnish Medicines Agency is the market surveillance authority referred to in Regulation (EU) 2019/1020 of the European Parliament and of the Council on market surveillance and compliance of products and amending Directive 2004/42/EC and Regulations (EC) No 765/2008 and (EU) No 305/2011, hereinafter the '*Market Surveillance Regulation*', in respect of products falling within the scope of the MD Regulation and the IVD Regulation.

The Radiation and Nuclear Safety Authority is responsible for supervising that medical devices comply with the requirements concerning the exposure of population to non-ionizing radiation referred to in section 161 and chapter 8 of the Radiation Act.

Section 38

Inspections

The Finnish Medicines Agency is competent to carry out the inspections referred to in the MD Regulation and the IVD Regulation and to perform an inspection to supervise other activities laid down in this Act.

For the purposes of carrying out an inspection, an inspector of the Finnish Medicines Agency has the right of access to all premises where activities referred to in the MD Regulation, the IVD Regulation or this Act are carried out or where information relevant to the inspection is kept. Inspections may also be conducted without prior notification. Inspections may also be carried out in premises used for residence of a permanent nature if there is reason to doubt that a medical

device, a performance study or a clinical investigation endangers human health and the performance of the inspection is necessary to protect human health or otherwise necessary to fulfil an obligation referred to in Article 44(4) or (7), Article 72(5) or in Article 93(1) or (3) of the MD Regulation or in Article 40(4) or (7), Article 68(5) or in Article 88(1) or (3) of the IVD Regulation.

All documents requested by the inspector that are necessary for carrying out the inspection must be produced in the inspection. Moreover, the inspector must be given, free of charge, any copies he or she might request of documents necessary to carry out the inspection. The inspector is also entitled to take photographs and make other recordings during the inspection.

The inspection is subject to section 39 of the Administrative Procedure Act, unless otherwise provided in the MD Regulation or the IVD Regulation. The inspector may issue orders to remedy the shortcomings noticed in inspections. The subject of inspection shall without delay take the required measures on account of an order issued in the inspection.

Section 39

Executive assistance by the police

The police shall, where necessary, provide executive assistance to the Finnish Medicines Agency for carrying out inspections.

Section 40

Right to use external experts

The Finnish Medicines Agency has the right to use external experts for assessing the features, safety and conformity of medical devices and devices to be investigated in a clinical investigation or performance study. An external expert shall possess the expertise and competence required for the tasks.

External experts may participate in inspections as well as investigate and test devices. The Agency is, however, itself responsible for the primary performance of inspections and on conclusions made in connection with supervision. An external expert may not participate in an inspection in premises used for residence of a permanent nature.

External experts are subject to the provisions on disqualification of the Administrative Procedure Act and the provisions on criminal liability for acts in office when they carry out tasks referred to in this Act. Provisions on liability for damages are laid down in the Tort Liability Act.

Section 41

Right to obtain a medical device for investigation by using a cover identity

The Finnish Medicines Agency has the right to obtain a medical device for investigation by using a cover identity if this is necessary for supervising the conformity of a medical device.

The manufacturer, authorised representative, importer, distributor, seller or another party which has placed a medical device on the market or dispensed it as well as a controller referred to in Article 4(7) of 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) shall be informed of the use of cover identity as soon as this is possible without compromising the purpose of the use of cover identity.

Section 42

Marketing ban

If a medical device has been marketed contrary to the provisions of section 10 of this Act, Article 7 of the MD Regulation or Article 7 of the IVD Regulation, the Finnish Medicines Agency may prohibit the party concerned from continuing or renewing marketing. The Agency may also order the recipient of the ban to correct incorrect or inadequate information used in marketing if this has to be considered necessary because of safety risks.

Section 43

Limiting access to online interface

If a medical device is non-compliant and poses a serious risk to human health, safety, the environment or property and if this is necessary to eliminate a serious risk, the Finnish Medicines Agency may order the service provider to delete content referring to the product from its website or other online interface referred to in Article 3(15) of the Market Surveillance Regulation. The Finnish Medicines Agency may, under the same conditions, order a service provider to give a clear warning to the end user about the risk caused by the product in connection with access to the online interface.

If the order referred to in subsection 1 has not been complied with, the Finnish Medicines Agency may:

1) order the service provider to prevent or limit access to the online interface or remove the online interface; or

2) order the administrator of domain register or a registrar to remove the domain from use or to register it under the Finnish Medicines Agency.

The Finnish Medicines Agency may also give the order referred to in subsection 1 or 2 as a temporary order. A temporary order is valid until the Agency gives its final decision in the matter. The Agency shall decide the matter urgently.

The Finnish Medicines Agency shall, before issuing an order referred to in subsections 1 to 3, give the decision recipient and the economic operator an opportunity to be heard, unless hearing cannot be organised as quickly as required by the urgency of the matter.

Section 44

Order to fulfil obligations

If an operator supervised by the Finnish Medicines Agency has neglected its obligations under the MD or the IVD Regulation or this Act, the Agency may order a deadline for fulfilling the obligation.

Section 45

Notice of a conditional fine and notice of enforced compliance

The effect of an order or a decision given by the Finnish Medicines Agency under the MD Regulation, the IVD Regulation or this Act may be enhanced by a notice of a conditional fine or a notice of enforced compliance. Provisions on the notice of a conditional fine and the notice of enforced compliance are laid down in the Act on Conditional Fines (1113/1990).

Enforced compliance is imposed by ordering that the main obligation must be complied with under the threat that the omitted work can be performed at the defaulter's cost.

If an order or decision given under the MD Regulation, the IVD Regulation or this Act has not been complied with within the set time limit, the Finnish Medicines Agency may fulfil the obligation at the cost of the party on which it has been imposed. If the Agency fulfils the obligation itself, the conditional fine imposed in the binding decision or order may not be ordered to be paid by a court.

Section 46

Right to receive and obligation to disclose information

In addition to the provisions laid down in the MD Regulation and the IVD Regulation on the right of a competent authority and a Member State to receive information, the following parties shall, upon request, give the information, documents and clarifications to the Finnish Medicines Agency

which are necessary for carrying out the tasks imposed on the Agency in the MD Regulation and the IVD Regulation or in this Act:

1) manufacturer;

2) authorised representative;

3) importer;

4) distributor;

5) professional user;

6) sterilisation service provider;

7) system or procedure pack assembler;

8) party which markets a medical device

9) person who professionally installs or maintains medical devices;

10) sponsor;

11) investigator and a member of an investigation group;

12) sponsor's legal representative;

13) sponsor's contact person;

14) party in whose premises a clinical investigation or a performance study is carried out;

15) operator other than those referred to in paragraphs 1 to 14 which is subject to the supervision under this Act.

The Agency has the right to obtain the information on patient documents necessary for implementing its supervisory tasks from the parties referred to in subsection 1 and the necessary information on patients from the monitoring system referred to in section 34.

The National Supervisory Authority for Welfare and Health, regional state administrative agencies, the Finnish Tax Administration, the Finnish Social Insurance Institution, the Radiation and Nuclear Safety Authority, the National Institute for Health and Welfare, the Patient Insurance Centre, the Finnish Safety and Chemicals Agency, the Finnish Customs, ethics committees and municipal authorities are obligated to disclose, upon request, the information to the Finnish Medicines Agency which is necessary for carrying out the tasks referred to in the MD Regulation, the IVD Regulation and in this Act.

If the National Supervisory Authority for Welfare and Health or a regional state administrative agency finds significant deficiencies related to medical devices or other significant shortcomings when carrying out its supervisory activities, these must be reported to the Finnish Medicines Agency. The National Supervisory Authority for Welfare and Health, regional state administrative agencies and other authorities mentioned in subsection 3 above may, at their own initiative, submit information they have discovered in their own activities on patients, social welfare clients and subjects of clinical investigations or performance studies to the Agency if they assess it to be necessary to submit the information in order to protect patients, clients or subjects.

If the Finnish Medicines Agency finds significant deficiencies or shortcomings related to the safety of patients or social welfare clients when carrying out its supervisory activities under the MD Regulation, the IVD Regulation or this Act, it must report these to the National Supervisory Authority for Welfare and Health or to the competent regional state administrative agency. The information may concern patients, social welfare clients and subjects of clinical investigations or performance studies if the Agency assesses it to be necessary to submit the information in order to protect patients, clients or subjects.

The information referred to in this subsection may be reported and the documents and clarifications submitted to the Finnish Medicines Agency, the National Supervisory Authority for Welfare and Health and to regional state administrative agencies notwithstanding secrecy provisions. The information, documents and reports shall be disclosed free of charge.

Section 47

Supervisory competence for medical devices under Medical Device Directives

The provisions of this Act on the supervision and competences of the Finnish Medicines Agency also apply to devices referred to in Article 120(3) and (4) of the MD Regulation.

If a medical device pursuant to the MD Directive or the AIMD Directive has been placed on the market or put into service before the date of application of the MD Regulation laid down in Article 123(2) of the MD Regulation, the supervision and competences of the Finnish Medicines Agency shall be subject to Article 93(3), (5) and (6), Article 94, Article 95(1) and (3), Article 95(4)(1), Article 97(1) and (2), Article 98(1) and Article 99(1) and (2) of the MD Regulation and sections 38 to 46 of this Act.

Section 48

Register of serious incidents

The Finnish Medicines Agency maintains a register of serious incidents. Reports of serious incidents filed by manufacturers and professional users are stored in the register. In addition, reports of serious incidents filed by professionals responsible for service and installation, other users and patients may also be stored in the register of serious incidents.

No other personal data than the names and contact details of the party filing a report and its contact persons are stored in the register of serious incidents.

Section 49

Notifications to the Finnish Medicines Agency and a device register

A manufacturer established in Finland, a manufacturer of custom-made devices, a system or procedure pack assembler, a sterilisation service provider, an authorised representative and an importer shall, before placing or making a device available on the market, submit a notification of their activities and device to the Finnish Medicines Agency. The Agency shall be notified of the operator's name, place of business and other necessary contact details.

In addition to the information referred to in subsection 1 above, the operators shall provide information to the Finnish Medicines Agency as follows:

1) a manufacturer, a manufacturer of a custom-made device and an importer shall notify the Agency of the devices that the operator intends to place on the market as well as their risk class, purpose, operating principle and the information that allows the devices to be identified;

2) a manufacturer and an importer shall submit a copy of a certificate issued by a notified body;

3) if necessary, a manufacturer shall provide the name and business place of the authorised representative;

4) a system or procedure pack assembler shall notify the Agency of the devices included in the system or procedure pack and their purpose as well as the information that allows the system or procedure pack to be identified;

5) a sterilisation service provider shall inform the Agency of the sterilisation methods used.

An operator which distributes devices to retailers, health care and social welfare operators and to other professional users and makes devices available on the market in Finland shall, before making the device available on the market, submit a notification of its activities and device to the Finnish Medicines Agency. The notification shall include the operator's name and business place as well as a list of devices to be made available on the market in Finland.

The operator referred to in subsection 3 above, which distributes devices and makes them available on the market in Finland, shall annually and at the request of the Finnish Medicines Agency provide information on the devices made available on the market which allows the devices to be identified.

The notification obligation referred to in subsection 3 above further applies to all distributors who make available on the market a device which they have imported to Finland and which is intended for self-testing or a medical device containing human tissue or substances derived from human blood or blood plasma.

The distributor referred to in subsection 5 above shall submit the following information and documents to the Finnish Medicines Agency:

1) the distributor's name and business place;

2) the devices made available on the market by the distributor and their classification as well as the information that allows the devices to be identified;

3) a copy of a certificate of conformity;

4) a copy of a certificate issued by a notified body;

5) instructions for use;

6) information on package labelling.

An operator engaged in device manufacture referred to in section 35 above and in section 27 of the Act on Certain Medical Specified in EU Directives only has to file a notification of its activities with the Finnish Medicines Agency.

The operator referred to in subsection 7 above shall inform the Finnish Medicines Agency of the following:

1) the operator's name, place or places of business and other necessary contact details;

2) information on the devices to be manufactured and their use, justification for their manufacture and information on where declarations of manufacture are available;

3) the name and contact details of the responsible person referred to in section 35.

If the operator engaged in device manufacture referred to in subsection 7 above is a municipality or joint municipal authority, the information on the whole municipality or joint municipal authority shall be submitted in one notification. If the operator engaged in manufacture is a private provider

of social or health services, the information shall be submitted in one notification in respect of the service provider registered in the register of private service providers pursuant to section 14a of the Act on Private Health Care (152/1990).

The operator referred to in subsections 1, 3 and 5 above shall, without delay, inform the Finnish Medicines Agency if it no longer places or makes a certain device available on the market. All operators subject to the notification obligation shall inform the Finnish Medicines Agency of substantial modifications to the information they have provided.

The Finnish Medicines Agency stores the information referred to in subsections 1 to 10 above in the device register maintained by it. The information shall be kept in the register for the period required by the supervision of devices and operators.

The Finnish Medicines Agency may issue further regulations on the submission of notifications, information to be submitted and procedures related to registration if the European database on medical devices referred to in Article 33 of the MD Regulation and in Article 30 of the IVD Regulation is not in operation.

Chapter 6

Supervision fee

Section 50

Supervision fee and its basis

The Finnish Medicines Agency collects an operator-specific supervision fee from operators subject to the notification obligation under section 49 to cover the costs resulting from device supervision. The supervision fee is determined according to the number of devices announced by the operator as follows:

a maximum of 10 devices	500 euros
11 to 50 devices	1 000 euros
51 to 100 devices	2 000 euros
101 to 500 devices	4 000 euros
over 500 devices	6 000 euros.

The supervision fee is determined according to the number of devices notified to the Finnish Medicines Agency by the end of the preceding year.

By derogation from the provisions of subsections 1 and 2, a supervision fee of 1 000 euros is collected annually from sterilisation service providers.

Section 51

Validity of payment obligation and maturity of payments

The obligation to pay supervision fees starts at the beginning of the year following the submission of information referred to in section 49. The payment obligation in respect of a modification affecting the fee starts at the beginning of the year following the submission of modified information. The payment obligation ends at the end of the year when the operator has informed the Finnish Medicines Agency that its activities have ceased or when the Agency has otherwise noted that the activities have ceased.

The supervision fee shall be determined for each calendar year, and it matures for payment annually at a time defined by the Finnish Medicines Agency but at the earliest on the last day of May. The Finnish Medicines Agency sends a payment decision to operators subject to payment obligation no later than 30 days before the due date.

Section 52

Increase of supervision fee and subsequent collection

If an operator has neglected its notification obligation under section 49, a supervision fee increased by 100% shall be collected from the operator.

Subsequent collection of the increased supervision fee may be carried out within three years starting from the beginning of the calendar year following the year when the payment obligation would have started.

The Finnish Medicines Agency may waive the collection of the increase of supervision fee if the omission relating to notification is minor.

Section 53

Recovery and interest of supervision fee

Fees and compensations to be paid to the government are directly enforceable. Provisions on their recovery are laid down in the Act on the Enforcement of Taxes and Charges (706/2007).

If a payment is delayed, interest for late payment shall be paid in accordance with section 4 of the Interest Act (633/1982). The Finnish Medicines Agency may, in lieu of the interest for late

payment, collect a five-euro penalty for late payment if the interest for delay would be smaller than this.

If part of the supervision fee is repaid because of an adjustment or appeal, an interest on refund shall be paid on the payment to be repaid under section 32 of the Act on Tax Collection (769/2016) from the payment date up to the refund date.

Section 54

Adjustment of supervision fee for the benefit of the party liable for payment

If an excessive supervision fee has been imposed on a party liable for payment because of an error, the payment decision shall be rectified unless the matter has been settled by an appeal decision. The adjustment for the benefit of the party liable for payment may be made within three years from the beginning of the calendar year following the year the payment was imposed.

Section 55

Adjustment of supervision fee for the benefit of the payee

If a supervision fee or part of it has not been imposed on a party liable for payment because of a calculation error or a similar mistake not caused by the party liable for payment or because the matter has not been investigated in some respect, the payment decision shall be rectified unless the matter has been settled by an appeal decision. The adjustment for the benefit of the payee can be made within a year from the beginning of the calendar year following the year when the payment was or should have been imposed.

Chapter 7

Appeal and penal provisions

Section 56

Appeal

A decision made by the Finnish Medicines Agency or a notified body under the MD Regulation, the IVD Regulation or this Act is subject to appeal. Provisions on appeal are laid down in the Administrative Procedure Act.

Provisions on appeal to an administrative court are laid down in the Administrative Judicial Procedure Act (808/2019).

Section 57

Penal provisions

The person who intentionally or due to gross negligence

1) places a medical device, an in vitro diagnostic medical device, an accessory or a product referred to in Annex XVI of the MD Regulation, makes it available on the market or puts it into service contrary to the MD Regulation, the IVD Regulation or this Act,

2) places a system or a procedure pack on the market contrary to Article 22 of the MD Regulation,

3) acts contrary to section 10 of this Act, Article 7 of the MD Regulation or Article 7 of the IVD Regulation,

4) substantially neglects an obligation laid down in Article 10(2), (4) or (5), Article 10(8)(1), Article 10(9), Article 10(10) to (13) or in Article 10(16)(1) of the MD Regulation or in Article 10(2) or (4), Article 10(7)(1), Article 10(8) to (12) or in Article 10(15)(2) of the IVD Regulation,

5) substantially neglects, when acting in the capacity of an authorised representative, to carry out the tasks agreed on in a mandate referred to in Article 11(3) of the MD Regulation or in Article 11(3) of the IVD Regulation,

6) substantially neglects an obligation laid down in Article 13(2)(1) or Article 13(6) of the MD Regulation or in Article 13(2)(1) or Article 13(6) of the IVD Regulation or in Article 14(2)(1) of the MD Regulation or in Article 14(2)(1) of the IVD Regulation,

7) substantially neglects the notification obligation laid down in Article 13(2)(2) or Article 13(6) or (8) of the MD Regulation or in Article 13(2)(2) or Article 13(6) or (8) of the IVD Regulation or the notification obligation laid down in Article 14(2)(2) or Article 14(4) or (5) of the MD Regulation or in Article 14(2)(2) or Article 14(4) or (5) of the IVD Regulation,

8) substantially neglects the reporting obligation laid down in Article 87(1) to (9), Article 87(11)(2), Article 88(1)(1) or in Article 89(5) of the MD Regulation or in Article 82(1) to (9), Article 82(11)(2), Article 83(1)(1) or in Article 84(5) of the IVD Regulation,

9) substantially neglects to perform the investigations related to a serious incident or device referred to in Article 89(1)(1) of the MD Regulation or in Article 84(1)(1) of the IVD Regulation or does not cooperate with the Finnish Medicines Agency or the notified body contrary to Article 89(1)(2) of the MD Regulation or Article 84(1)(2) of the IVD Regulation,

10) substantially neglects the obligation to draft a field safety notice pursuant to Article 89(8) of the MD Regulation or Article 84(8) of the IVD Regulation,

11) substantially neglects the reporting obligation referred to in section 33,

12) presents untrue or misleading information in a document related to an application for a clinical investigation or performance study submitted for assessment by authorities or for ethical review and the information essentially influences the acceptability of the investigation or study,

13) carries out a clinical investigation or performance study without an authorisation issued under Article 70(7)(b) of the MD Regulation, Article 66(7)(b) of the IVD Regulation or section 21, subsection 3, 4 or 8 or section 22, subsection 3 or 4 of this Act or substantially contrary to the authorisation requirements or carries out a clinical investigation or performance study without a favourable opinion of the competent ethics committee or substantially contrary to the requirements set forth in the opinion,

14) carries out a clinical investigation or performance study even though the Finnish Medicines Agency has suspended the clinical investigation under Article 76(1) of the MD Regulation or Article 72(1) of the IVD Regulation,

15) carries out a clinical investigation substantially contrary to the provisions on informed consent laid down in Articles 63 to 65 of the MD Regulation, in Articles 59 to 61 of the IVD Regulation or in sections 25 to 27 of this Act,

16) substantially neglects the notification obligation referred to in Article 77(1) to (3) of the MD Regulation or in Article 73(1) to (3) of the IVD Regulation,

17) substantially neglects the reporting obligation laid down in Article 77(5), Article 80(2) or (3) or in Article 80(4)(1) of the MD Regulation or in Article 73(5), Article 76(2) or (3) or in Article 76(4)(1) of the IVD Regulation,

18) records, processes or stores information substantially contrary to Article 72(3) or Article 80(1) of the MD Regulation or Article 68(3) or Article 76(1) of the IVD Regulation,

19) seeks to influence the subject or other person referred to in section 28, subsection 1 by financial or other inappropriate ways contrary to Article 62(4)(k), Article 64(1)(d), subparagraph d of Article 65 or subparagraph c of Article 66 of the MD Regulation, Article 58(5)(k), Article 60(1)(d), Article 61(1)(d) or subparagraph d of Article 62 of the IVD Regulation or section 28 of this Act,

shall be sentenced for *a violation of provisions on medical devices* to a fine, unless a more severe punishment for the act is provided elsewhere in the law.

For conduct punishable in accordance with subsection 1 above, the person into whose sphere of responsibility the act or negligence belongs shall be sentenced. In determining this, consideration shall be given to the position of the said person, to the nature and extent of his or her duties and powers and to his or her participation in the emergence and continuation of the unlawful situation otherwise.

If there is reason to suspect that this Act has been violated, the Finnish Medicines Agency shall report the matter to the criminal investigation authority. Reporting may be waived if the suspected offence is minor or if it is established that the act has been caused by excusable negligence or inconsideration and the public interest does not necessitate reporting.

Chapter 8

Miscellaneous provisions

Section 58

Exemption order

The Finnish Medicines Agency may grant, upon application, a fixed-term exemption order for placing a medical device on the market or putting it into service even though its conformity has not been assessed according to the MD Regulation or the IVD Regulation if

1) the device is necessary for protecting public health or alleviating or treating a patient's disease or injury;

2) no other similar CE-marked device is available; and

3) the applicant shows that the device fulfils the relevant general safety and performance requirements.

In addition, the order referred to in subsection 1 can be granted if

1) the order is necessary in exceptional circumstances to protect public health;

2) the order is necessary to ensure adequate availability of devices; and

3) the Agency has an adequate clarification that the device fulfils the relevant general safety and performance requirements.

The Finnish Medicines Agency may include conditions for the safety of the device and its use in the exemption order.

Provisions on the competence of the Ministry of Social Affairs and Health to allow a medical device to be placed on the market and its deployment when faced with the threat of an epidemic and in other similar disruptions in health care are laid down in section 75 of the Communicable Diseases Act (1227/2016).

Chapter 9

Entry into force and transitional provisions

Section 59

Entry into force

This Act enters into force on 19 July 2021.

This Act applies to devices falling into the scope of the IVD Regulation and to the operators' obligations as of 26 May 2022. If, however, the above-mentioned Regulation is applied to an in vitro diagnostic medical device, economic operator, authority or notified body referred to in the Regulation, to another matter or operator governed by the Regulation or to a party's right or obligation pursuant to the Regulation, this Act shall apply to such device, operator or right or obligation already before the above-mentioned date.

Section 8 of the Act shall apply to economic operators referred to in the section in respect of in vitro diagnostic medical devices as of 26 May 2022.

A performance study on an in vitro diagnostic medical device may be carried out in accordance with the IVD Regulation and this Act already before 26 May 2022.

If the electronic system referred to in Article 73 of the MD Regulation or in Article 69 of the IVD Regulation is not in operation, an application for or a notice of a clinical investigation or performance study shall be submitted to the Finnish Medicines Agency.

If the application for a performance study is filed before 26 May 2022, the time limits laid down for the Member State and sponsor in Article 66 of the IVD Regulation shall not apply. In this case, the Finnish Medicines Agency shall announce within 10 days from the submission of the application if the study does not fall within the scope of the IVD Regulation or if the application is deficient. The Agency may request the sponsor to provide additional clarifications or supplement the application. A time limit shall be set for the request. The Agency shall inform the sponsor within 5 days from the receipt of additional clarifications or supplements whether the study falls within the scope of the Regulation and whether the application includes the necessary documents. If the Agency considers that the study falls within the scope of the Regulation and the application includes the

necessary documents, this date is considered as the validation date of the application. The Agency shall make a decision referred to in section 22, subsection 4 within 45 days from the validation date. This time limit may be extended by 20 days for the purpose of consulting with experts. The notice referred to in section 22, subsection 5 of the Act shall be given on the validation date.

Subsection 4 of section 34 of the Act shall apply as of 26 May 2023.

Section 35 of the Act shall apply to the manufacture of in vitro diagnostic medical devices by health institutions as of 26 May 2022.

The notification referred to in subsections 1 and 6 of section 49 of the Act shall be submitted to the Finnish Medicines Agency within five months from the entry into force of this Act. This obligation also applies to an operator which before the entry into force of this Act had submitted a notification of its activities and device to a competent authority in accordance with section 18, subsection 1 of the Medical Devices Act that was in force when this Act entered into force.

The notification obligation laid down in section 49, subsections 1 and 2 of this Act applies to manufacturers and importers of devices pursuant to the MD Regulation and the IVD Regulation until the European database on medical devices referred to in Article 33 of the MD Regulation and in Article 30 of the IVD Regulation is in operation and the operator has registered its activities and device in it in accordance with the provisions of the Regulations.

The distributor referred to in section 49, subsections 3 and 5 of the Act shall give a notification of its activities to the Finnish Medicines Agency within five months from the entry into force of this Act. The information on the devices distributed by the distributor shall also be up-to-date no later than on 30 November 2022. The obligation also applies to an operator which before the entry into force of this Act had submitted a notification of its activities and device to a competent authority in accordance with section 18, subsection 2 of the Medical Devices Act that was in force when this Act entered into force.

If the operator referred to in section 49, subsection 1, 3 or 5 places or makes a device available on the market in accordance with the MD Regulation or the IVD Regulation, a prior notice shall be submitted.

The supervision fee pursuant to section 50 of the Act is collected for the first time in 2022. In 2022, the supervision fee to be collected from all distributors referred to in section 49, subsections 3 and 5 is 500 euros.

In Naantali on 15 July 2021

President of the Republic of Finland

Sauli Niinistö

Minister of Family Affairs and Social Services Krista Kiuru