Government of Iceland
Ministry of Health

Act on Medical Devices, No. 132/2020.

Where mention is made in this Act of 'the minister' or 'the ministry' without further definition, the reference intended is to the Minister of Health or to the Ministry of Health, which is responsible for the implementation of this Act. Information on the division of responsibilities between ministries according to a presidential decree may be found here.

SECTION I
Aim, legislative transpositions and scope.

Article 1

Aim.

The aim of this Act is to ensure the quality and safety of medical devices, with public safety as the guiding principle, and to ensure that the production, maintenance and use of medical devices are in accordance with the best professional knowledge at any given time.

Article 2

Legislative transpositions.

The provisions of Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 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, of Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, and of Regulation (EU) 2020/561 of the European Parliament and of the Council of 23 April 2020 amending Regulation (EU) 2017/745 on medical devices, as regards the dates of application of certain of its provisions as adopted in the EEA Agreement shall have the force of law in Iceland with the adaptations resulting from Decisions of the EEA Joint Committee No. 288/2019 of 13 December 2019 and No. 90 of 18 June 2020 (*cf.* also Protocol 1 on Horizontal Adaptations to the EEA Agreement and the European Economic Area Act, No. 2/1993, in which the Protocol was given the force of law).

Article 3

Scope.

This Act covers the production, importing, distribution, sale, placing on the market, market surveillance, maintenance and use of medical devices and their monitoring.

The Act applies both to medical devices with an intended medical purpose and to those without an intended medical purpose in accordance with Annex XVI of the Medical Device Regulation.

In cases of doubt as to whether a device is to be considered a medical device, the Icelandic Medicines Agency shall resolve the question in accordance with further provisions of the Regulations.

If, when all the properties of a product are taken into account, it is considered to be a medical device in accordance with a decision by the Icelandic Medicines Agency, yet it also falls under the definition of a product of another type which is subject to other legislation, the provisions of this Act shall apply to it.

SECTION II
Definitions.

Article 4

Definitions.

For the purposes of this Act, the following words and terms have the meanings given below:

1. *Recall*: Any measure aimed at achieving the return of a device that has already been made available to the end user.
2. *Person responsible for regulatory compliance*: An individual who is responsible for ensuring compliance by the manufacturer with regulations; this person may be a recognised compliance officer (*cf.* Article 15 of the Regulations; see item 26).
3. *Sponsor*: Any individual, company, institution or organisation which takes responsibility for the initiation, for the management and setting up of the financing of the clinical investigation.
4. *Making available on the market*: Any supply of a device, other than an investigational device, for distribution, consumption or use on the market in the course of a commercial activity, whether in return for payment or free of charge.
5. *CE marking of conformity or 'CE marking'*: A marking by which a manufacturer indicates that a device is in conformity with the applicable requirements set out in this Act and the regulations.
6. *Distributor*: Any natural or legal person in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service.
7. *Unique Device Identifier (UDI)*: A series of numeric or alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market.
8. *Single-use device*: A device that is intended to be used on one individual during a single procedure.
9. *Reprocessing*: A process carried out on a used device in order to allow its safe reuse including cleaning, disinfection, sterilisation and related procedures, as well as testing and restoring the technical and functional safety of the used device.
10. *EU declaration of conformity*: A declaration to the effect that the requirements specified in the Regulations have been fulfilled in relation to the device that is covered by the declaration (*cf.* Article 19 of the Medical Devices Regulation (MDR) and Article 17 of the In Vitro Diagnostic Medical Devices Regulation, IVDR).
11. *Manufacturer's specifications*: Specifications from the manufacturer regarding maintenance and repairs which are set out in the user's manual and maintenance instructions accompanying a device.
12. *Manufacturer*: A natural or legal person who manufactures or fully refurbishes a device (as defined in point 31 of Article 2 of the Medical Devices Regulation) or has a device designed, manufactured or fully refurbished and markets that device under its name or trademark.
13. *Healthcare institution*: An institution where healthcare services are provided.
14. *Importer*: Any natural or legal person established within the European Economic Area that places device from a non-EEA country on the market.
15. *Withdrawal*: Any measure aimed at preventing a device in the supply chain from being further made available on the market.
16. *Implantable device*: Any device, including those that are partially or wholly absorbed, which is intended:
    a. to be totally introduced into the human body, or
    b. to replace the epithelial surface or the surface of the eye, by clinical intervention and which is intended to remain in place after the procedure.

The term ‘implantable device’ also covers any device intended to be partially introduced into the human body by clinical intervention and intended to remain in place after the procedure for at least 30 days.

17. *Implant card*: Information which the manufacturer of an implantable device is required to provide together with the device (*cf.* Article 18 of the Medical Devices Regulation and Article 19 of this Act).
18. *Clinical investigation*: Any systematic investigation involving one or more human subjects, undertaken to assess the safety or performance.
19. *Medical device*: any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:
    a. diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
    b. diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
    c. investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
    d. providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.

    The following products shall also be regarded as medical devices:
    a. devices for the control or support of conception;
    b. products specifically intended for the cleaning, disinfection or sterilisation of devices, accessories for medical devices, products intended for the control or support of conception and products listed in Annex XVI to the Medical Devices Regulation.
20. *In vitro diagnostic medical device*: Any medical device which is a reagent, reagent product, calibrator, control material, kit, instrument, apparatus, piece of equipment, software or system, whether used alone or in combination, intended by the manufacturer to be used in vitro for the examination of specimens, including blood and tissue donations, derived from the human body, solely or principally for the purpose of providing information on one or more of the following:
    a. concerning a physiological or pathological process or state,
    b. concerning congenital physical or mental impairment,
    c. concerning a predisposition to a medical condition or disease,
    d. to determine the safety and compatibility with potential recipients,
    e. to predict treatment response or reactions,
    f. to define or monitor therapeutic measures.

    Specimen receptacles shall also be deemed to be in vitro diagnostic medical devices.
21. *Label*: Written, printed or graphic information appearing either on the device itself or on the packaging of each unit or on the packaging of multiple devices.
22. *User*: Any healthcare professional or lay person who uses a device.
23. *Instructions for use*: Information provided by the manufacturer to inform the user of a device's intended purpose and proper use and of any precautions to be taken.
24. *Medical Devices Regulation (MDR)*: Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 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, including its Annexes.
25. *In Vitro Diagnostic Regulation (IVDR)*: Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU, including its Annexes.
26. *The Regulations*: The MDR and the IVDR (see points 24 and 25).
27. *Economic operator*: A manufacturer, an authorised representative, an importer, a distributor or the person referred to in Article 22(1) and 22(3) of the MDR.

28. *Conformity assessment*: The process demonstrating whether the legal and regulatory requirements relating to a medical device have been fulfilled.
29. *Placing on the market*: The first making available of a device, other than an investigational device, on the market in the EEA.
30. *Healthcare professionals' clinics*: Workstations of independently active healthcare professionals where health services are provided, with or without state participation in the costs.
31. *Putting into service*: When a medical device, other than an investigational device, has been made available to the final user as being ready for use for the first time for its intended use on the market.
32. *Notified body*: A conformity assessment body designated by the IMA in accordance with this Act and the Regulations.
33. *Device*: Any medical device (*cf.* points 19 and 20).
34. *Investigational device*: A device that is assessed in a clinical investigation.
35. *Authorised representative*: Any natural or legal person established within the European Economic Area (EEA) who has received and accepted a written mandate from a manufacturer, located outside the EEA, to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under the Regulations.

SECTION III
Supervision and the role of the Icelandic Medicines Agency.

Article 5
Supervision.

The Minister shall exercise supervision of matters under this Act.

Article 6
Role of the Icelandic Medicines Agency.

The Icelandic Medicines Agency (IMA) is the competent authority in the sense of Article 101 of the MDR and Article 96 of the IVDR.

The IMA shall see to the application of the Regulations, of this Act, of special provisions in legislation that apply to medical devices and of other rules covering these matters.

The IMA shall see to the monitoring of medical devices under this Act, the Regulations and other rules.

The IMA may examine individual cases and take decisions on them on its own initiative or in accordance with submissions or tip-offs.

The IMA shall set itself rules on procedure, for example as regards the examination of applications for clinical investigations of medical devices and the examination of reports of serious incidents.

Other tasks of the IMA include the following.

1. To issue certificates requested by the manufacturers of medical devices.
2. To monitor clinical investigations of medical devices.
3. To maintain a register of manufacturers, authorised representatives and importers based in Iceland.
4. To maintain a register of distributors.
5. To promote consciousness and understanding among healthcare professionals, users and patients of the importance of informing the IMA in the event of a suspicion of a serious incident relating to medical devices as listed in point (a) of Article 87 (1) of the MDR and point (a) of Article 82(1) of the IVDR.
6. To inform manufacturers of all suspected serious incidents; if the manufacturer confirms that an incident has occurred, the IMA shall ensure that measures are taken with the aim of preventing a recurrence of such incidents.
7. To receive and register reports of serious incidents and faults from manufacturers, distributors, healthcare professionals, users and patients. The IMA shall maintain a register of such reports and of faults in medical devices.
8. To share information on serious incidents and malfunctions, as appropriate.
9. To recall or withdraw products from the market in accordance with this Act.

10. To collaborate with other competent authorities in the field of medical devices within the EEA.
11. To monitor advertisements for medical devices in accordance with this Act.
12. To attend to other tasks relating to the application of this Act and the Regulations and rules issued under the Act, including collaboration with foreign entities in the field of medical devices.

SECTION IV
Requirements which medical devices are to fulfil.

Article 7
Safety.

Medical devices shall be in conformity with the requirements stated in this Act and in Section II of the Regulations, in addition to the general safety and performance requirements set out in Annex I to the Regulations.

Medical devices may only be placed on the market and put into service if their design, manufacture and finishing fulfil the requirements of the Regulations and of this Act.

The composition, manufacture, packaging, distribution and maintenance of medical devices shall be such that the device works as is assumed in the manufacturer's instructions.

The Regulations and this Act shall apply to medical devices that are designed and produced and used within healthcare institutions.

The Minister may, in a regulation, lay down further requirements regarding the quality, safety and labelling of medical devices.

Article 8
EU declaration of conformity.

In the EU declaration of conformity, the manufacturer shall declare that the medical device is in conformity with the requirements which it is supposed to fulfil and which are set out in the Regulations.

By making an EU declaration of conformity, the manufacturer warrants that the device conforms with the Regulations and this Act. The manufacturer of the device shall keep the EU declaration of conformity up to date.

EU declarations of conformity shall, as a minimum, contain the information set out in Annex IV to the Regulations.

Article 9
CE markings.

Before a medical device is placed on the market, sold or put into service, it must be CE marked in accordance with the further provisions of the Regulations and the procedure set out in Annexes IX-XI to the Regulations. Devices shall be CE marked in accordance with Part II of Chapter V of the Regulations, together with their Annexes.

The CE marking shall be affixed visibly, legibly and indelibly. Where such affixing is not possible or not warranted on account of the nature of the device, the CE marking shall be affixed to the packaging. The CE marking shall also appear in any instructions for use and on any sales packaging.

The IMA may take a medical device off the market even though it is marked in accordance with paragraph 1 if it comes to light that the device has hazardous properties.

It shall not be necessary to mark devices in accordance with paragraph 1 if they are used exclusively as exhibits at trade fairs, exhibitions, promotions or similar events, or in demonstrations and the like, providing that a visible sign clearly indicates that such devices are intended for presentation or demonstration purposes only and cannot be made available until they have been marked in compliance with this Act and the further provisions laid down in the Regulations.

Article 21 of the MDR shall apply as regards the marking of medical devices intended for clinical investigations and custom-made devices.

Article 10

Advertising.

Medical devices may be advertised in Iceland, subject to the restrictions laid down in the Regulations and in this Act.

Advertisements shall at all times be presented in an objective manner and shall give satisfactory information about the device, its properties and its use. The user or patient shall be informed of potential risks involved in the use of the device in line with its intended purpose.

The Minister may issue regulations setting out further rules on advertising, e.g. prohibiting a particular method of advertising or prohibiting the advertising of specific categories of medical devices.

Article 11

Claims.

In the labelling, instructions for use, making available, putting into service and advertising of devices, it shall be prohibited to use text, names, trademarks, pictures and figurative or other signs that may mislead the user or the patient with regard to the device's intended purpose, safety and performance, by:

1. ascribing functions and properties to the device which the device does not have;
2. creating a false impression regarding treatment or diagnosis, functions or properties which the device does not have;
3. failing to inform the user or the patient of a likely risk associated with the use of the device in line with its intended purpose;
4. suggesting uses for the device other than those stated to form part of the intended purpose for which the conformity assessment was carried out.

Article 12

Labels and instructions for use.

Each device shall be accompanied by the information needed to identify the device and its manufacturer, and by any safety and performance information in accordance with the further instructions of Chapter III of Annex 1 to the Regulations.

Information under paragraph 1 shall appear on the device itself, on the packaging or in the instructions for use, in accordance with the further instructions of Chapter III of Annex 1 to the Regulations.

Information and instructions for use accompanying medical devices intended for use by the public shall normally be in Icelandic.

The Minister may issue regulations[1)] on the application of this provision in further detail, including as regards the language of instructions for use accompanying devices intended for use by the public.

[1)] *Regulation No. 630/2022.*

Article 13

Classification.

Devices shall be divided into classes I, IIa, IIb and III, taking into account the intended purpose of the devices and their inherent risks. Classification shall be carried out in accordance with Annex VIII to the Regulations.

Any dispute between the manufacturer or, as appropriate, the authorised representative, and the party involved shall be referred to the IMA in accordance with the further provisions of Chapter V of the Regulations.

Procedure in the examination of disputes regarding classification shall be subject to the further provisions of Chapter V of the Regulations.

Article 14

Safe handling of medical devices.

The natural or legal person, or healthcare institution, which owns a medical device and is responsible for its operation or use, shall be liable for matters including:

1. the correct use of the device and the competence of the user in accordance with the manufacturer's instructions;
2. the satisfactory post-use cleaning, etc., and storage of the device;
3. the carrying out of maintenance and repair services and ensuring that these are performed by competent parties so as to ensure users' safety;
4. the installation and connection of the medical device in accordance with the manufacturer's instructions in order to ensure the correct application and safety of the device.

Article 15

Training of users of medical devices.

The natural or legal person, or healthcare institution, which owns a medical device and is responsible for its operation or use, shall ensure that users receive the instruction and training necessary for the correct and safe use of the device and that they receive information about any hazards that accompany its use.

Such instruction and training shall take place at times including when the device is purchased and when new workers are engaged, and by maintaining users' skills. This instruction and training shall be systematic, and shall be documented.

Article 16

Use of medical devices.

Medical devices shall be used in accordance with their intended purpose and the manufacturer's instructions. Users shall have a knowledge of the principal aspects of the device's performance and shall have received at least minimum training in the handling and use of the device so as to ensure successful use and ensure that patients, users or others are not endangered by the device.

The IMA shall monitor to ensure that medical devices are used in accordance with their intended purpose and the Regulations, this Act and other rules applying to medical devices. The IMA may examine how medical devices are being used and it may demand information on the training of users and certificates attesting to their competence.

To protect the safety of users and patients, the Minister may issue regulations specifying that only healthcare professionals with certain qualifications and experience may use specific medical devices in classes IIa, IIb og III, and also devices covered by Annex XVI to the MDR.

Article 17

Maintenance and re-use of medical devices.

The natural or legal person, or healthcare institution, which owns a medical device and is responsible for its operation or use shall, if so required by the manufacturer's specifications, be obliged to have regular quality and safety checks and maintenance of the device carried out in accordance with the requirements laid down in the manufacturer's specifications and the best available professional knowledge at any given time. Such regular checks, and also all maintenance of the device, shall be carried out by authorised professions with the necessary professional knowledge, or who have undergone approved training by the manufacturer of the device in order to maintain it. Such checks and maintenance of medical devices shall be documented.

The IMA shall monitor to ensure that maintenance of medical devices is carried out in compliance with the manufacturer's specifications and the best available professional knowledge at any given time. Information on checks and maintenance shall be available to the IMA and the agency may demand the necessary information from the parties specified in paragraph 1, or the person who carries out maintenance, and make the examinations and tests necessary to establish the safety of a device.

The Minister may determine in a regulation how the maintenance and re-use of medical devices are to be organised.

Article 18

Single-use devices and their reprocessing.

The Minister shall issue regulations on the reprocessing and further use of single-use devices, including as regards within healthcare institutions.

Article 19

Information to be supplied with implantable devices; implant cards.

The manufacturer of an implantable device shall provide the following information together with the device as is specified in further detail in Article 18 of the MDR:

1. information allowing the identification of the device, including the device name, serial number, lot number, the UDI, the device model, as well as the name, address and the website of the manufacturer;
2. any warnings, precautions or measures to be taken as are further prescribed in the Regulations;
3. information about the expected lifetime of the device and any necessary follow-up;
4. any other information to ensure safe use of the device by the patient.

The manufacturer shall be responsible for ensuring that information under paragraph 1 is clear and accessible. Information shall normally be in Icelandic. The IMA shall set rules concerning the language requirements covering information to be supplied with implantable devices under this paragraph.

The manufacturer shall be responsible for updating the information as appropriate, and the information shall be accessible on the manufacturer's website.

The manufacturer shall provide healthcare institutions or the workplaces of healthcare professionals with the information required under point 1 of paragraph 1 on an implant card which shall accompany the device.

Healthcare institutions shall be responsible for giving patients their implant cards. Healthcare institutions shall make the information covered in paragraph 1 accessible to patients who have been implanted with devices.

Certain implantable devices are exempt from the requirements set out in paragraphs 1–4 (*cf.* Article 18(3) of the MDR).

Article 20

Clinical investigations.

Clinical investigations on medical devices may be carried on receipt of a licence from the IMA and the National Bioethics Committee.

Clinical investigations shall be subject to the further provisions of the Regulations in Chapter VI and Annexes XIV and XV of the MDR and Annex XIV to the IVDR.

Applications for clinical investigations shall be submitted to the IMA in accordance with further provisions set out in Chapter VI of the Regulations. The IMA and the National Bioethics Committee shall assess plans in accordance with further provisions set out in Chapter VI of the Regulations.

The IMA and the National Bioethics Committee shall, as appropriate, monitor to ensure that investigations are carried out in accordance with the Regulations and with this Act.

The further provisions of Chapter VI of the Regulations shall apply as regards informed consent of subjects, registration of serious adverse events and coordinated assessment procedures in clinical investigations of medical devices.

The Minister may issue regulations setting out further provisions on the conduct of clinical investigations of medical devices, including as regards insurance and communications between the IMA and the National Bioethics Committee in connection with clinical investigations of medical devices.

SECTION V

Obligations of economic operators.

Article 21

Obligations of the manufacturer.

The obligations of the manufacturer are laid down in the Regulations and in this Act.

Before placing their devices on the market or putting them into service, manufacturers shall ensure that they have been designed and manufactured in compliance with the requirements laid down in the Regulations and in this Act.

The manufacturer shall carry out a clinical evaluation of medical devices, or performance assessments in the case of in vitro diagnostic medical devices, in compliance with the requirements laid down in Chapter VI of the Regulations and the annexes thereto.

Manufacturers of devices other than custom-made devices shall draw up and keep up to date technical documentation for those devices. The technical documentation shall be such as to allow the conformity of the device with the requirements of this Act and the Regulations to be assessed. The technical documentation shall include the elements set out in Annexes II and III to the Regulations.

Manufacturers shall ensure that devices are accompanied by the information specified in Chapter III of Annex I to the Regulations. This information shall be accessible to patients and users; it shall be indelible, easily legible and clearly comprehensible.

If the circumstances described in Article 16 of the Regulations obtain, the distributor, importer or another natural or legal person shall assume the obligations incumbent on manufacturers under the Regulations.

Manufacturers shall take measures to ensure that they are able to honour compensation claims directed towards them connected with incidents relating to medical devices for which they are responsible under the Regulations and this Act. Measures taken by manufacturers shall be proportionate to the risk category and type of device and the size of the undertaking. The Minister may issue regulations setting out further provisions covering manufacturers' measures under this provision.

Article 22

Surveillance by the manufacturer.

Manufacturers of devices, other than investigation devices, shall establish, document, implement, maintain and update quality management systems as provided for in Article 10 of the Regulations.

Manufacturers shall establish, document, implement and maintain systems for risk management as provided for in the Regulations.

Manufacturers shall implement a post-market surveillance system for medical devices and draw up a plan in compliance with Section VII of the Regulations.

Manufacturers shall prepare post-market surveillance reports on medical devices in accordance with the further provisions of Section VII of the Regulations. Reports shall be updated when necessary and submitted to the IMA at its request.

Article 23

Person responsible for regulatory compliance.

Manufacturers shall have in their employment at least one person responsible for regulatory compliance who possesses the requisite expertise in accordance with the further provisions of Article 15 of the Regulations; this person shall be responsible for ensuring compliance with the rules set out in the Regulations and in this Act.

Micro and small enterprises are not required to have the person responsible for regulatory compliance within their organisation; however, they shall have such a person at their disposal in accordance with the further provisions of Article 15 of the Regulations.

Official representatives shall have a person responsible for regulatory compliance at their disposal in accordance with the further provisions laid down in Article 15 of the Regulations.

Article 24

Authorised representatives.

Where the manufacturer of a device is not established in the European Economic Area, the device may only be placed on the market within the area if the manufacturer designates an authorised representative.

Designation and obligations of authorised representatives shall be in compliance with the further provisions of Articles 11 and 12 of the Regulations.

Article 25

Importers' obligations.

Importers may only place on the market medical devices that are in compliance with the Regulations and the requirements of this Act.

Before a device is made available on the market, importers shall verify that the following requirements have been met:

1. that the device is CE marked and that the EU declaration of conformity has been drawn up;
2. that the manufacturer is specified and that the manufacturer has designated an authorised representative in accordance with Article 11 of the Regulations;
3. that the device is labelled in compliance with this Act and the Regulations and that it is accompanied by the requisite instructions for use;
4. that, where applicable, a UDI has been assigned by the manufacturer in compliance with the Regulations.

In other respects, importers shall meet the requirements laid down in Article 13 of the Regulations.

Article 26

Distributors' obligations.

When making a device available on the market, distributors shall, in the context of their activities, ensure that the device conforms with the valid requirements of the Regulations and of this Act.

Before placing or offering a device on the market, distributors shall verify that the following requirements have been met:

1. that the device has been CE marked and that the EU declaration of conformity of the device has been drawn up;
2. that the device is accompanied by the information to be supplied by the manufacturer in accordance with Article 10(11) of the Regulations;
3. that, in the case of imported devices, the importer has met the requirements of Article 13(3) of the Regulations;
4. that, where applicable, a UDI has been assigned by the manufacturer in conformity with the Regulations.

In other respects, distributors shall meet the requirements laid down in Article 14 of the Regulations.

Article 27

Notified bodies.

The Accreditation Division of the Intellectual Property Office shall assess the competence and qualifications of those who wish to acquire licences to carry out conformity assessments of medical devices. The Accreditation Division of the Intellectual Property Office shall, after receiving the comments of the IMA, be authorised to designate notified bodies to the IMA.

The IMA shall notify the EFTA Surveillance Authority, the European Commission and other EEA Member States of the notified bodies (*cf.* the further instructions of Chapter IV of the Regulations).

If a notified body no longer meets the requirements on which its designation by the Accreditation Division of the Intellectual Property Office was based, it may commission the IMA to recall its notification to the EFTA Surveillance Authority, the European Commission and other EEA Member States.

The further provisions of Chapter IV of the Regulations, with Annexes, and of the Accreditation (Etc.) Act shall apply regarding notified bodies, the designation and application procedure, monitoring and the reassessment of notified bodies, the review of notified body assessment of technical documentation, changes to designations and notifications, etc.

The Minister may issue regulations on the further application of this provision, for example as regards the designation and application procedure.

SECTION VI
Identification and traceability of devices, registration, etc.

Article 28

Electronic system for registration of economic operators.

Manufacturers of medical devices, other than custom-made devices, official representatives and importers shall register in an electronic system in compliance with the further provisions of Chapter III of the Regulations.

The IMA shall confirm registration under paragraph 1 and assign a single registration number (SRN) in compliance with the further requirements of Chapter III of the Regulations.

Distributors shall register with the IMA in accordance with further rules set by the agency.

Article 29

Identification and traceability of medical devices.

Distributors and importers shall co-operate with manufacturers or authorised representatives to achieve an appropriate level of traceability of devices.

Economic operators shall be able to identify the following to the IMA, for the period referred to in Article 10(8) of the MDR and in Article 10(7) of the IVDR:

1. any economic operator to whom they have directly supplied a device;
2. any economic operator who has directly supplied them with a device;
3. any health institution or healthcare professionals' clinics to which they have directly supplied a device.

Article 30

European database on medical devices.

Iceland is a member of the European database on medical devices ('Eudamed').

Eudamed comprises the following electronic systems:

1. the Unique Device Identification system (UDI system) referred to in Chapter III of the Regulations;
2. the UDI database referred to in Chapter III of the Regulations;
3. the electronic system for the registration of economic operators referred to in Chapter III of the Regulations;
4. the electronic system on notified bodies and on certificates referred to in Chapter V of the Regulations;
5. the electronic system on clinical investigations referred to in Chapter VI of the Regulations;
6. the electronic system on vigilance and post-market surveillance referred to in Chapter VII of the Regulations;
7. the electronic system on market surveillance referred to in Chapter VII of the Regulations.

The IMA, notified bodies, economic operators and sponsors shall register data in Eudamed as provided for in further detail in the Regulations.

Information registered in the database shall be accessible by the IMA, notified bodies, economic operators, sponsors and the public to the extent specified in the Regulations.

Article 31

Unique Device Identification (UDI) system.

The UDI system is described in Part C of Appendix VI to the Regulations. The system identifies and facilitates the traceability of devices other than custom-made devices and investigational devices.

The UDI system and the UDI database shall be subject to the further provisions of Chapter III of the Regulations.

Article 32

Registration in the UDI system.

Before placing a device on the market, the manufacturer shall assign to the device and, if applicable, to all packaging, a UDI in compliance with the further provisions of Chapter III of the Regulations.

The manufacturer shall ensure that the information referred to in Part B of Annex VI to the Regulations device in question is correctly submitted and transferred to the UDI database referred to in Article 28 of the MDR. The manufacturer shall maintain an up-to-date register of all UDIs that he has assigned in accordance with the further provisions of the Regulations.

The obligations of economic operators as regards registration in the UDI system shall be subject to the further provisions of Chapter III of the Regulations.

Article 33

Registration of implantable medical devices.

Healthcare institutions shall maintain electronic registers of the UDIs of all medical devices that they have delivered or received and that fall within implantable devices in class III (*cf.* Annex VIII to the MDR).

Healthcare professionals' clinics shall maintain electronic registers of the UDIs of all devices that they have delivered or received and that fall within implantable devices in class III (*cf.* Annex VIII to the MDR).

Economic operators shall maintain electronic registers of the UDIs of all devices that they have delivered or received and that fall within implantable devices in class III or devices that come under Article 27(11)(a) of the MDR.

Details of patients who have received implantable devices or been implanted with such devices shall be recorded in the database provided for under paragraphs 1 and 2. The name, ID Number and other personal details of each patient shall be recorded.

The IMA may demand that the parties named in paragraphs 1 and 2 grant it access to the database, or deliver data from it, including personally identifiable data such as the name, ID Number and other personal details of the patient.

The Minister may issue a regulation setting out rules on the further implementation of the registration of implantable medical devices, for example as regards how registration is to take place and what exactly is to be recorded in the electronic database.

SECTION VII
Surveillance and sanctions.

Article 34

Surveillance.

The IMA shall monitor compliance with the provisions of this Act and of the Regulations, unless other provisions are laid down in this Act or in the Regulations.

The IMA shall, at its own initiative or acting on tip-offs, examine cases concerning the safety of medical devices and the obligations of the parties covered by this law and the Regulations.

The IMA shall exercise market surveillance in accordance with Part 3 of Chapter VII of the Regulations.

The IMA shall take a decision on whether a communication received by the agency gives sufficient grounds for investigation. When processing cases under this Act, the IMA may rank them in order of priority.

The IMA may process personal data, including personal data of a sensitive nature on whether an individual has been implanted with a medical device, in order to conduct surveillance and discharge other obligations under this Act, providing that it meets the requirements of the Personal Data Act.

The police shall assist the IMA if necessary in connection with the investigation of cases and the application of the legal remedies prescribed in this Act.

Article 35

Reporting of serious incidents; obligation to take corrective action.

Those who manufacture, sell, own or use medical devices and know of non-conformities, faults or non-activation which could cause, or have caused, damage to health, shall be obliged to report such things immediately to the IMA.

If economic operators have reason to think that medical devices which are in their keeping and which are intended for placement on the market, or which are on the market, are not safe or in some other respect do not comply with the Regulations or the law, they shall immediately take the corrective actions necessary to bring the medical devices in question into line with the Regulations and this Act, or recall or withdraw the medical devices, as appropriate. Furthermore, the economic operator shall inform the IMA immediately of all such cases that arise.

The IMA shall be informed of all serious incidents and, as appropriate, corrective actions taken, in accordance with the further provisions of Chapter VII of the Regulations.

The police shall inform the IMA of accidents and other events which they investigate if there is reason to suspect that the cause may be attributed to a medical device.

Manufacturers' reports of serious incidents and field safety corrective actions taken shall be sent via the electronic system on vigilance and on post-market surveillance described in Chapter VII of the Regulations.

The IMA shall maintain a register of notifications of serious incidents and take the appropriate measures in conformity with this section and Chapter VII of the Regulations.

Article 36

Obligation to provide information.

The IMA may demand that economic operators, healthcare professionals, users of devices and other persons covered by this Act provide the information and materials considered necessary, in the agency's opinion, for the examination of individual cases. Demands for information may be made orally or in writing, and the information shall be provided within a reasonable period as determined by the agency.

The IMA may demand all information and materials it considers necessary to demonstrate conformity of a device with the requirements of this Act and the Regulations. The IMA may demand that an economic operator deliver to it, without charge, a device, or a sample of a device, or that it grant access to a device within a reasonable period, which shall be determined by the agency.

Natural persons, economic operators, healthcare institutions and users of medical devices shall provide the assistance and information requested in any given instance.

The IMA may demand information and materials from other government authorities, including the customs authorities, irrespective of their non-disclosure obligations.

Natural persons, economic operators, healthcare institutions shall inform the IMA, at its request, of the medical devices for which the party in question is responsible. The IMA shall maintain a register of medical devices, and may set further rules on the application of the obligation to provide information and to restrict it to medical devices in specific risk categories.

Article 37

Monitoring of workplaces and confiscation.

The IMA may visit places where medical devices are situated. These may be the place of manufacture, the place of sale (whether wholesale or retail) or other places where medical devices are used. It shall not be permitted access for this purpose to private residences or other comparable places without the consent of the owner or person entitled to use the premises without a court order.

The IMA may take such samples and carry out such investigations and tests as may be necessary in connection with monitoring.

The IMA may, in the course of monitoring or investigating cases, carry out the necessary investigation of the workplaces of economic operators and prohibit the continued use, sale and distribution of medical devices, and seize documentation or medical devices when there is good reason to believe that a violation of the Regulations and of this Act has occurred.

Article 38

Recall and prohibition on the sale of devices.

The IMA may, by a decision based on reasons, recall, withdraw, take off the market or prohibit the sale or supplying of a device if it does not comply with the rules or requirements that are made of medical devices, for example as regards safety, labelling, instructions, certificates, conformity declarations or test or examination reports that are laid down in the Regulations and this Act, providing that it is not possible to apply other less drastic remedies.

If an economic operator demonstrably obstructs investigation or monitoring by the IMA under this Section, or fails to give the IMA satisfactory information regarding the safety of a medical device, the IMA may recall, withdraw, or remove the medical device from the market, or prohibit its sale or supply until the investigation is completed.

If there is reason to suspect that a medical device is not in conformity with the rules applying to the safety of the device, the IMA may temporarily prohibit the sale or supply of the device while an investigation is carried out. Such temporary prohibitions shall not last longer than four weeks. Prohibitions may, however, be extended for up to two weeks at a time if this is necessitated due to special circumstances pertaining to the investigation.

If the IMA considers that a medical device is particularly dangerous, it may demand the immediate recall of all exemplars of the device on the market.

Procedure by the IMA under this provision shall be in accordance with the further provisions of Part 3 of Chapter VII of the Regulations. Other aspects of procedure and legal remedies shall be in accordance with Sections IV and V of the Product Safety and Public Market Surveillance Act, No. 134/1995, and the Administrative Procedure Act.

Article 39

Fees.

The IMA may charge fees for the following:

1. The issue of certificates (*cf.* point 1 of paragraph 6 of Article 6).
2. Monitoring the use of medical devices (*cf.* Article 16).
3. Monitoring of maintenance of medical devices (*cf.* Article 17).
4. Assessment of applications for clinical investigation on medical devices (*cf.* paragraph 3 of Article 20).
5. Registration of distributors (*cf.* paragraph 3 of Article 28).
6. Monitoring of economic operators of medical devices (*cf.* Article 34).

The Minister shall, after receiving proposals from the IMA, issue a tariff of charges for services, surveillance and tasks that are entrusted to the agency under this Act. Monetary amounts of fees shall take account of the cost of the services and the execution of individual tasks; fees shall be based on an operating plan in which the factors on which the fees are determined are set out, with reasons. Fees may not be higher than this cost.

Article 40

Per diem fines.

When a party fails to comply with instructions within a certain period, the IMA may impose per diem fines until the situation is rectified.

Per diem fines may amount to as much as ISK 50,000 each day. When the amount of a fine is determined, factors such as the extent and seriousness of the violation, how long the situation has lasted and whether the violation has been repeated.

The IMA's decisions regarding per diem fines may be enforced. If a fine under this Article has not been paid within 30 days of the IMA's decision, arrears interest shall be paid on the fine amount. Decisions on the calculation of arrears interest shall be taken in accordance with the Interest and Indexation Act. Uncollected per diem fines imposed up to the date of payment shall not be waived even though the party

pays the charge in question later, unless the IMA decides this specifically. Fines imposed under this Article shall be paid to the state Treasury after deduction of the cost of collection.

Article 41

Administrative fines.

The IMA may impose administrative fines on natural or legal persons which violate the provisions on:

1. Safety requirements (*cf.* Article 7)
2. CE- markings (*cf.* Article 9).
3. Advertising (*cf.* Article 10).
4. Claims (*cf.* Article 11).
5. Labels and instructions for use (*cf.* Article 12).
6. Safe handling of medical devices (*cf.* Article 14).
7. Training of users of medical devices (*cf.* Article 15).
8. Use of medical devices (*cf.* Article 16).
9. Maintenance of medical devices (*cf.* Article 17).
10. Clinical investigations (*cf.* Article 20).
11. Obligations of the manufacturer (*cf.* Article 21).
12. Surveillance by the manufacturer (*cf.* Article 22).
13. Person responsible for regulatory compliance (*cf.* Article 23).
14. Importers' obligations (*cf.* Article 25).
15. Distributors' obligations (*cf.* Article 26).
16. Electronic system for registration of economic operators (*cf.* Article 28).
17. Identification and traceability of medical devices (*cf.* Article 29).
18. Registration in the UDI system (*cf.* Article 32).
19. Registration of implantable medical devices (*cf.* Article 33).
20. Reporting of serious incidents and obligation to take corrective action (*cf.* Article 35).
21. Obligation to provide information (*cf.* Article 36).

The Minister may issue regulations determining the monetary amount of administrative fines for violations of individual provisions of this Act within the frame laid down in paragraph 4.

Where the monetary amount of fines has not been determined in regulations, then when fines are determined, consideration shall be given to the seriousness of the violation, how long it has lasted, willingness on the part of the perpetrator to cooperate and whether the violation has been repeated. Consideration shall also be given to whether it is reasonable to conclude that the violation was committed in the interests of an undertaking and whether the violation could have been prevented by management and surveillance. The IMA may determine heavier fines if the party derived economic benefit from the violation. The monetary amount of the administrative fine shall then be determined as up to twice as much as the amount gained by the party through the violation against this Act or regulations issued hereunder; nevertheless, it shall be within the framework laid down in paragraph 4.

Administrative fines imposed on natural persons may lie in the range ISK 10,000 to ISK 10 million. Administrative fines imposed on legal persons may lie in the range ISK 25,000 to ISK 25 million.

The due date for the payment of administrative fines is 30 days after the decision to impose the fine was taken. If an administrative fine has not been paid within 15 days of the due date, arrears interest on the fine amount shall be paid, calculated from the due date. Decisions by the IMA on administrative fines are enforceable in law, and fines are paid to the state Treasury after deduction of the cost of imposition and collection. Decisions and calculations in connection with arrears interest are subject to the Interest and Indexation Act.

Administrative fines shall be applied irrespective of whether the violation was committed intentionally or through negligence. When assessing the monetary amount of fines, the IMA shall take into account whether the violation was committed intentionally or through negligence.

The IMA's decisions are final at the administrative level and no appeals may be lodged against them to the Minister. The deadline for bringing a case before the courts is three months from the date on which the

decision to impose the administrative fine was taken. Registration of an appeal action shall defer enforcement action.

Article 42

Right to abstain from self-incrimination.

In an action against a natural person which could result in the imposition of an administrative fine or the laying of a charge to the police, any person who is reasonably suspected of having committed a violation of the law shall have the right not to answer questions or make over materials or items unless it is possible to exclude the possibility that doing so could be of significance in determining whether he/she committed the violation. The IMA shall give suspected persons guidance on the exercise of this right.

Article 43

Limitation.

The authority of the IMA to impose administrative fines under this Act shall expire when five years have elapsed since the termination of the conduct in question.

The period defined in paragraph 1 shall be interrupted when the IMA informs a party of the initiation of investigations into a suspected violation. Interruption of the period shall have effects in law vis-à-vis all persons involved in the violation.

Article 44

Fines or imprisonment.

Where no more severe punishment is prescribed for the violation in other acts of law, fines or imprisonment of up to two years shall be imposed for violations of the provisions on:

1. Safety requirements (*cf.* Article 7).
2. CE markings (*cf.* Article 9).
3. Claims (*cf.* Article 11).
4. Labels and instructions for use (*cf.* Article 12).
5. Safe handling of medical devices (*cf.* Article 14).
6. Training of users of medical devices (*cf.* Article 15).
7. Use of medical devices (*cf.* Article 16).
8. Maintenance of medical devices (*cf.* Article 17).
9. Clinical investigations (*cf.* Article 20).
10. Obligations of the manufacturer (*cf.* Article 21).
11. Surveillance by the manufacturer (*cf.* Article 22).
12. Importers' obligations (*cf.* Article 25).
13. Distributors' obligations (*cf.* Article 26.)
14. Registration of implantable medical devices (*cf.* Article 33).
15. Reporting of serious incidents and obligation to take corrective action (*cf.* Article 35).

Fines may be imposed on a legal person even where it is not possible to demonstrate guilt on the part of its management or employees, or other individuals working in its service, providing that the violation resulted, or could have resulted, in an advantage for the legal person. However, the legal person shall not be punished in the case of an accident. In the same way, fines may be imposed on legal persons if their managers or employees, or other individuals working in their service, are convicted of violations.

Article 45

Actionability, seizure, attempted violations and acting as an accessory.

Violations of this Act are punishable by fines or imprisonment, irrespective of whether they are committed intentionally or through negligence.

Direct or indirect profits resulting from violations of this Act that are punishable by fines or imprisonment may be seized under a court order.

Attempted violations of this Act, or acting as an accessory in a violation, shall be punishable under the General Penal Code.

Article 46

Charges to the police.

The IMA may lay charges to the police relating to violations.

Where an alleged violation of this Act would be punishable by both administrative fines and penalties, the IMA shall assess whether a charge relating to the matter is to be made to the police or whether it is to be concluded by an administrative decision taken by the agency. In the event of major violations, the IMA shall be obliged to refer them to the police. Violations are regarded as major if the violation was perpetrated in a particularly reprehensible manner or under circumstances which greatly increase the actionability of the violation. Furthermore, the IMA, at any stage of the matter, refer cases involving violations of this Act for a criminal investigation. Consistency shall be observed in the resolution of comparable cases.

Charges laid by the IMA shall be accompanied by copies of the materials on which the suspicion of the violation is based. The provisions of Section IV-VII of the Administrative Procedure Act shall not apply regarding decisions by the IMA to lay charges to the police.

The IMA may provide the police and the prosecution authorities with all materials acquired by the agency that relate to the violations specified in paragraph 2. The IMA may take part in actions by the police that are connected with the investigation of the violations specified in paragraph 2.

The police and the prosecution authorities may provide the IMA with all materials acquired that relate to the violations specified in paragraph 2. The police may take part in actions by the IMA that are connected with the investigation of the violations specified in paragraph 2.

If a prosecutor considers there are no grounds for initiating a case in connection with alleged criminal conduct which is also punishable under the Administrative Procedure Act, he/she may send, or return, the case to the IMA for examination and the taking of a decision.

Article 47

Right of appeal.

Unless otherwise stated in this Act, appeals may be lodged to the Minister against administrative decisions taken under this Act. The Administrative Procedure Act shall apply as regards the right of appeal procedure in cases.

SECTION VIII
Regulations, commencement, etc.

Article 48

Authorisation for the issue of regulations.

The Minister may issue regulations setting out further provisions on the application of this Act, for example as regards the following:

1. Requirements regarding the quality, safety and labelling of medical devices (*cf.* paragraph 5 of Article 7).
2. Advertising (*cf.* paragraph 3 of Article 10).
3. Labels and instructions for use (*cf.* paragraph 4 of Article 12).
4. Whether the use of specific medical devices in risk classes IIa, IIb and III is to be restricted to healthcare professionals with certain qualifications and experience (*cf.* paragraph 3 of Article 16).
5. The maintenance and re-use of medical devices (*cf.* paragraph 3 of Article 17).
6. Single-use devices and their re-processing (*cf.* Article 18).
7. The conduct of clinical investigations of medical devices (*cf.* paragraph 6 of Article 20).
8. Measures to be taken by manufacturers to ensure that they are able to honour compensation claims directed towards them connected with incidents relating to medical devices (*cf.* paragraph 7 of Article 21).
9. Notified bodies (*cf.* paragraph 5 of Article 27).

10. The registration of implantable medical devices (*cf.* paragraph 6 of Article 33).
11. The monetary amount of administrative fines imposed for violations of individual provisions of this Act (*cf.* paragraph 2 of Article 41).

The IMA may set rules on its tasks under this Act.

The IMA shall regularly publish the rules it sets under this Act so that they are accessible to the public.

The Minister may publish as a regulation[1)] the implementation rules of the European Union on medical devices as referred to in the Regulations, with adaptations under the Agreement on the European Economic Area and the Convention Establishing the European Free Trade Association.

[1)] *Regulation No. 630/2022. Regulation No. 907/2022, cf. 1275/2022 and 341/2023.*

Article 49

Commencement.

This Act takes effect on 26 May 2021. …

Article 50

Amendments to other acts.

…

[*This translation is published for information only.*
The original Icelandic text is published in the Law Gazette.
In case of a possible discrepancy, the original Icelandic text applies.]