VELFERÐARRÁÐUNEYTIÐ

Ministry of Welfare

Act on Medical Devices, No. 16/2001,
as amended by Act No. 76/2002, No. 88/2008, No. 28/2011, No. 59/2016 and No. 59/2016.

CHAPTER I
General Provisions.

Article 1

Scope.

This Act applies to the manufacture, sale, marketing, market surveillance, maintenance and use of medical devices and surveillance by health authorities of such devices.

Article 2

Objective.

The objective of this Act is to prevent damage to users of medical devices and to ensure that the production, maintenance and use of medical devices is consistent with the best available professional expertise at any time.

Article 3

Definitions.

For the purpose of this Act:

1. [*Medical device:* means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by the manufacturer to be specifically used for diagnosis or treatment and is necessary to use the device correctly, intended by the manufacturer to be used for men for the purpose of:
    a. diagnosis, prevention, monitoring, treatment or alleviation of diseases,
    b. diagnosis, monitoring, treatment, alleviation or compensation for an injury, disability or impaired capacity,
    c. investigation, change or replacement of an organ or of a physiological process,
    d. controlling of conception,

    but does not serve its main purpose in or on the human body with methods concerning pharmacology, immunology or metabolism, but its effect may be supported by such methods.

    In the event of any doubt as to whether a device or item constitutes a medical device, the Icelandic Medicines Agency shall decide.][1)]
2. *Manufacturer*: means the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his/her own name, regardless of whether these operations are carried out by that person himself/herself or on his/her behalf by a third party.

    A natural or legal person who assembles, packages, processes, fully refurbishes and/or labels one or more products and/or assigns to them their intended purpose as a device with a view to their being placed on the market under his/her own name, shall constitute a manufacturer.

    A person who assembles or adapts devices already on the market to their intended purpose for an individual patient shall not constitute a manufacturer.

3. *User*: means a person who needs a medical device owing to a disease, disability or impaired capacity, who works with medical devices or who is responsible for [medical devices][1)] supervision and/or maintenance.
4. *Clinical investigation*: means research on humans for the purpose of obtaining information and/or verifying that medical devices, in normal use, conform to basic requirements on characteristics and performance, as provided for in the EU Directives which form a part of the Agreement on the European Economic Area [and the Convention establishing the European Free Trade Association].[2)] Clinical investigations include assessment of undesired side-effects of medical devices.

[1)] Act No. 59/2016, Article 5. [2)] Act No. 76/2002, Article 29.

CHAPTER II
Requirements to be fulfilled by Medical Devices.

Article 4
Safety Requirements.

Medical devices shall be manufactured, used, maintained and monitored so as to meet the safety requirements provided for herein and in regulations issued hereunder for the purpose of protecting the life and health of users. The assembly, manufacture packaging and maintenance of medical devices shall be such that the device will perform as indicated in the manufacturer's instructions.

A medical device may only be placed on the market and taken into use if its design, manufacture and packaging does not pose a risk to the user.

The same provisions shall apply to medical devices which are designed and manufactured within health institutions.

Article 5
Labelling.

Before a medical device is placed on the market, sold or taken into use, it shall be labelled pursuant to the rules of the European Union on medical devices, which are part of the Agreement on the Economic Area, or pursuant to requirements laid down in agreements which Iceland has entered into with parties outside the European Economic Area.

[The Icelandic Medicines Agency][1)] may remove a medical device from the market, even if it is labelled in accordance with paragraph 1, if it appears that the device has dangerous qualities.

An exception may be granted from paragraph 1 in respect of devices which are intended only for display at trade fairs, exhibitions, in demonstrations etc., for clinical testing, *cf.* Article 9, or which are custom-made for an individual person.

[1)] Act No. 28/2011, Article 17.

Article 6
Instructions for use.

All medical devices shall be accompanied by necessary information from the manufacturer and instructions for safe use. Instructions needed to use the device in a safe manner shall, to the extent possible, be included on the device itself and/or on its packaging. Medical devices intended for the use of the public shall be accompanied by instructions in Icelandic.

Article 7
Treatment.

The owner of a medical device is responsible for its correct use and the qualifications of the user. Furthermore, the owner shall ensure adequate disposal and storage and that maintenance and repair services are carried out by authorised party in such a way that the safety of the user is ensured.

Article 8

Registration.

[The Icelandic Medicines Agency][1)] shall maintain a register of parties operating enterprises in Iceland which manufacture medical devices or are responsible for the marketing of such devices.

[1)] Act No. 28/2011, Article 17.

[Article 8 a

Issue of Certificates.

The Icelandic Medicines Agency shall execute the issue of certificates, required by the manufacturer of medical devices.][1)]

[1)] Act No. 59/2016, Article 6.

Article 9

Clinical Investigation.

The manufacturer shall submit an application for clinical testing of a medical device to [the Icelandic Medicines Agency][1)], which shall ensure that the conduct of the investigation is compatible with rules of good practice and rules on patients' rights, including provisions on research and on the evaluation of the Science Ethics Committee.

[The Icelandic Medicines Agency][1)] may halt the conduct of clinical investigation in the event of non-observance of the terms governing clinical investigations.

[1)] Act No. 28/2011, Article 17.

CHAPTER III
Surveillance and Procedure.

Article 10

Surveillance.

[The Icelandic Medicines Agency][1)] is responsible for surveillance of the safety of medical devices. Surveillance refers, on the one hand, to market surveillance, i.e. ensuring that medical devices placed on the market comply with safety requirements and requirements on labelling pursuant to Article 5, and on, the other hand, surveillance of proper maintenance of medical devices and of the use of medical devices. [Surveillance refers, furthermore, to surveillance of manufacturer to follow the provisions of this Act and regulations issued under this Act and address the manufacture of medical devices.][2)] [The Icelandic Medicines Agency][1)] may assign part of this surveillance to other parties.

Surveillance bodies may request necessary data for their surveillance, take samples and carry out the investigations and tests regarded as necessary to prevent damage caused by medical devices. [Surveillance bodies may furthermore visit any place where there are medical devices, whether it is manufacturing site, sales premises, whether it is wholesale or retail trade, or site where the devices are used. For this purpose, it is unauthorised to enter dwelling or such places without consent of the owner or the possessor of the housing, except after obtaining a court order.][2)] Manufacturers, importers, sellers, owners and users of medical devices shall provide the assistance and information needed and requested at any time.

[1)] Act No. 28/2011, Article 17. [2)] Act No. 59/2016, Article 7.

Article 11

Obligation to notify.

Parties who manufacture, sell, own or use medical devices and are aware of deviations, defects or non-functionality which could cause or has caused damage to the health of a user, or death, is under obligation to notify [the Icelandic Medicines Agency.][1)]

[1)] Act No. 28/2011, Article 17.

Article 12

Fees.

[The Icelandic Medicines Agency may charge fees for:

1. registration of parties operating enterprises in Iceland and which manufacture medical devices or are responsible for marketing such devices, *cf.* Article 8,
2. issue of certificates, *cf.* Article 8 a,
3. evaluation on application for clinical testing of medical devices, *cf.* Article 9,
4. market surveillance, *cf.* paragraph 1 of Article 10,
5. assessment at manufacturers and importers of medical devices, *cf.* paragraph 1 of Article 10.

The Minister issues, on the recommendation of the Icelandic Medicines Agency, a tariff for the service, monitoring and tasks that the Agency has been entrusted to handle under this Act. The amount of the fee shall be based on the cost of the service and conduct of single tasks and shall be based on operating budget, including arguments for the items which the decision of fee is based on. The fee may not be higher than that cost. The tariff shall be published in Section B of the Law and Ministerial Gazette. The fee me be collected by attachment.][1)]

1) Act No. 59/2016, Article 8.

Article 13

Procedure, Legal Recourse and Sanctions.

Procedure and legal recourse of surveillance authorities pursuant to Article 10 shall be subject to Article 10 of Chapters IV and V of Act No. 134/1995, on product safety and public market surveillance, as applicable.

...[1)]

1) Act No. 88/2008, Article 233.

CHAPTER IV
Other Provisions.

Article 14

The Minister may, by government regulation[1)], provide for the further implementation of this Act, e.g. as regards the safety of medical devices, labelling, instructions for use, registration, clinical investigation and the obligation to notify.

1) Regulation No. 934/2010. Regulation No. 320/2011.

Article 15

This Act shall enter into force immediately.

...

Transitional Provisions

I.

Medical devices which are labelled in accordance with Council Directive 76/764/EC may be placed on the market, sold or used until 30 June 2004.

Devices for biosample analysis meeting safety requirements prior to the entry into force of this Act may be placed on the market, sold or taken into use until 7 December 2003.

II.

This Act shall be subject to review within five years of their entry into effect.

[*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.]