VELFERÐARRÁÐUNEYTIÐ

Ministry of Welfare

REGULATION
on Medical Devices, No. 934/2010.

CHAPTER 1
Scope and Definitions.
Article 1
Scope.

This Regulation covers the production, sales, marketing, use and maintenance of medical devices and their parts, and the health authority surveillance of such devices. The Regulation applies equally to the devices and their parts. Medical devices and parts are in this Regulation called devices.

When a device is intended to administer a medicinal product in the understanding of Article 5 of the Medicinal Products Act, No. 93/1994, as amended, then such a device shall be covered by this Regulation, with the reservation of the provisions of the Medicinal Products Act, No. 93/1994, with respect to medicinal products.

Where a device according to paragraph 3 is placed on the market in such a manner that the device and the medicinal product constitute one integrated manufactured product, which shall only be used in this combination and is disposable, then the provisions of the Medicinal Products Act, No. 93/1994, shall apply to that product. The relevant basic requirements in Annex I in accompanying document 1 to this Regulation shall apply to the safety and to the attributes of the device with respect to its functionality.

Where part of a device is a substance that when used on its own could be considered a medicinal product in the understanding of the Medicinal Products Act, No. 93/1994, and could have other effects on the body and those that the device has, then the device shall be assessed and its use authorised on the basis of this Regulation.

If a medical device which contains as a constituent part, a substance that can be judged, if used on its own, to constitute substance of a medicinal product or products, which is produced from human blood or blood plasma in the understanding of the Medicinal Products Act, No. 93/1994, and that substance, which hereafter is called „derivative from human blood“, can have other effects on the human body than one could expect from the device itself, then such a device shall be assessed in accordance with this Regulation.

Where the manufacturer intends the device to be used in accordance with the provisions of personal protection equipment in Regulation No. 501/1994, on the type of personal protection equipment, and in accordance with this Regulation, then the device shall also fulfil the provisions of the relevant basic requirements for health protection and safety in Regulation No. 501/1994, on the type of personal protection equipment.

This Regulation is a specialised regulation in the understanding of Regulation No. 270/2008, on electromagnetic compatibility.

This Regulation does not apply to:

a) Devices for in vitro diagnostic devices, as they are covered by the Regulation on for in vitro diagnostic devices.
b) Surgically implanted devices, as they are covered by the Regulation on active surgically implanted medical devices.

c) Medicinal products covered by the Medicinal Products Act, No. 93/1994, as amended. In deciding whether a product is covered by this act or this Regulation, the basic functionality of the product shall first and foremost be taken into account.
d) Cosmetics, as they are covered by Regulation No. 748/2003, on cosmetics.
e) Human blood, human blood products, human plasma or blood cells of human origin or devices which incorporate at the time of placing on the market such blood products, plasma or cells, with the exception of the devices specified in paragraph 6 of Article 2.
f) Transplants or tissues or cells of human origin or products incorporating or derived from tissues or cells of human origin, with the exception of the devices specified in paragraph 6 of Article 2.
g) Transplants or tissues or cells of animal origin, unless a device is manufactured utilizing animal tissue which is rendered non-viable or nonviable products derived from animal tissue.
h) Use and maintenance of x-ray diagnosis or treatment devices or the use of radioactive materials, as they are covered by Act No. 44/2002, on Radiation Protection.
i) Devices specified in paragraph 1 of Article 25 where they are not intended to come into contact with the human body or are only intended to come into contact with undamaged skin.

Article 2
Definitions.

In this Regulation the meanings of the following concepts are as follows:

1) *Medical device*: Any instrument, equipment, appliance, software, substance or other article, whether it is used alone or in combination, including the software that a manufacturer intends specifically for use in diagnosis and/or treatment and which is necessary for proper use of the device, and intended by the manufacturer for use for humans in order to:
   – diagnose, prevent, investigate, treat or alleviate an illness,
   – diagnose, monitor, treat or repair damage to the body, handicap and/or limited capacity,
   – investigate, change or replace the functionality of the anatomy or physiological activity,
   – control pregnancy,

   that does not perform its main function in or on the human body by pharmacological, immunological or metabolic means, but may support its function with such means.
2) *Accessories*: An accessory is not a medical device, but is intended by the manufacturer intends for specialised use with a medical device in order for it to be used in the manner the manufacturer intends.
3) *A medical device for diagnosis* (*in vitro)*: A medical device that is a reactant, a product of a reactant, calibrator, control material, kit, instrument, apparatus, equipment or system, whether it is 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:
   – concerning a physiological or pathological state, or
   – concerning a congenital abnormality, or
   – to determine the safety and compatibility with potential recipients, or
   – to monitor therapeutic measures.

   Specimen receptacles are considered to be in vitro diagnostic medical devices, whether vacuum-type or not, and that are specifically intended by their manufacturers for the primary containment and preservation of specimens derived from the human body for the purpose of in vitro diagnostic examination.

   Products for general laboratory use are not in vitro diagnostic medical devices unless such products, in view of their characteristics, are specifically intended by their manufacturer to be used for in vitro diagnostic examination.
4) *Custom-made devices*: A device that is custom-made according to a written prescription from a doctor who has the required education and competence and that on his/her responsibility is designed with special attributes and that is only intended for one specific patient.

   In addition to this, any individual can issue such a prescription should he/she have the authority to do so based on his/her vocational training and competence.

A mass-produced device that has to be adapted to specific requirements of a doctor or of another professional is not considered to be a custom-made device.

5) *A device intended for clinical investigation*: A device intended to be used by a doctor, suitably educated and competent, for testing, as is specified in item 2.1 of Annex X in accompanying document 1 to this Regulation in a clinically adequate environment.
   For the performing of clinical investigation, all other persons that have the authority to perform tests on the basis of their vocational training and competence are considered the equivalent of an educated and competent doctor.
6) *Kit*: A prepared package of items, which are usually all sterilised and which are packaged for specific operations. Individual items in the package can be from more than one manufacturer.
7) *Manufacturer*: A natural or legal person that bears responsibility for the design, manufacture, packing and labelling of a device before it is placed on the market in his/her name, whether he/she performs these actions himself/herself or where a third party does so on his/her behalf.
   The obligations of this Directive to be met by manufacturers also apply to the natural or legal person who assembles, packages, processes, fully refurbishes and/or labels one or more ready-made 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. This paragraph does not apply to persons who package or refurbish devices that are on the market for specific use for specific patients, and that are not manufacturers in the understanding of paragraph 1 of this item.
8) *Intended use*: The use for which the device is intended according to the information provided by the manufacturer on labels, in instructions and/or promotional material about the product.
9) *The user*: The person that needs medical devices because of illness, handicap or impaired capacity, that works with medical devices or has supervision of them and/or maintains them.
10) *Marketing*: To offer a device in the first instance, in return for payment or without charge, except for a device for clinical investigation, with the intention of distributing and/or using it on markets within the EEA, whether it is new or completely refurbished.
11) *To take into use*: When a device has become accessible to end users and is ready for the first time for intended use on the EEA market.
12) *Recognised representative*: A natural or legal person based in the EEA who is specially authorised by the manufacturer and who represents him/her where parties based in the EEA can communicate with him/her instead of with the manufacturer regarding the obligations of the latter according to this Regulation.
13) *Authorised parties*: Parties that are authorised to perform tasks regarding those methods specified in Article 11.
14) *Legally competent authorities*: In Iceland, the Medical Director of Health, *cf.* Article 10 of Act No. 16/2001, on Medical Devices.
15) *Sterilisation*: Sterilisation, were all micro-organisms have been removed or killed on and/or in a defined area or part.
16) *Responsible party*: The party who is responsible for marketing medical devices in this country. The responsible party can be a manufacturer or importer. The responsible party bears certain obligations in excess of those borne by other sellers.
17) *CE-Conformity marking*: Marking to confirm that the product fulfils all specified basic requirements in regulations and harmonised standards in the EEA.
18) *Surveillance*: Surveillance of the safety of medical devices is the responsibility of the Medical Director of Health, *cf.* Article 10 of the Act on Medical Devices, No. 16/2001, as amended. Among other things surveillance means surveillance of the market, i.e. surveillance to determine whether the medical devices marketed in Iceland fulfil safety requirements and requirements for labelling, *cf.* Article 8, and on the other hand surveillance to determine whether maintenance is performed on the medical devices, *cf.* Article 17, and surveillance of the use of medical devices, *cf.* Article 16. The Medical Director of Health is authorised to delegate specific surveillance tasks to other parties.
19) *Harmonised standard*: A standard that has been written with reference to the basic requirements of the European Committee for Standardisation (CEN) or of European Committee for Electro-technical Standardisation (CENELEC) on behalf of the EEA.

20) *Declaration of conformity*: A declaration by a manufacturer of his/her responsibility for a product conforming to standards or other documented requirements.
21) *Cell*: The smallest structural unit of a living form that can live independently and can renew itself in a suitable environment.
22) *Tissue*: An aggregate of cells and/or extra-cellular constituents.
23) *Derivative*: A substance derived from animal tissue with a manufacturing process, such as collagen, gelatine or monoclonal antibodies.
24) *Non-viable*: Non-viable means having no potential for metabolism multiplication.
25) *Transmissible agents*: Transmissible agents means unclassified pathogenic entities, prions and such entities as bovine spongiform encephalopathies agents and scrapie agents.
26) *Reduction and elimination or removal*: A process by which the number of transmissible agents is reduced, eliminated or removed in order to prevent infection or pathogenic reaction.
27) *Inactivation*: A process by which the ability to cause infection or pathogenic reaction by transmissible agents is reduced.
28) *Source country*: The country in which the animal was born, has been reared and/or has been slaughtered.
29) *Starting materials*: Raw materials or any other product of animal origin out of which, or with the help of which, the devices referred to in paragraph 1 of Article 25 are produced.
30) *Hip, knee and shoulder joint replacement*: An implantable part of the total system of replacement of a joint that is intended to create the capability of movement similar to that of natural hip, knee and shoulder joints. Additional parts, i.e. screws, wedges, plates and tools are not included here.
31) *Clinical data*: Information on safety and/or operation that is collected with use of a device Clinical data is collected:
    – from clinical tests of the device in question or
    – from clinical tests or other observations, that are described in scientific papers, on a similar device where it is possible to demonstrate that that device is equivalent to the device in question or
    – from published and/or unpublished reports on other clinical experience, either on the device in question or on a similar device where it is possible to demonstrate that the device is equivalent to the device in question here.
32) *Subcategories of devices*: A group of devices with common intended usage or that are based on the same technology.
33) *General category of devices*: A group of devices with the same or similar intended use or that are based on common technology which makes it possible to categorise them in a general manner but which does not reflect specialised attributes.
34) *Disposable devices*: A device that is only intended to be used once and for one patient.

See further definitions in Annex IX in accompanying document 1 to this Regulation on the criteria for categorising medical devices.

CHAPTER II
Marketing, market surveillance, use and basic requirements.

Article 3
Marketing and use.

It is only authorised to market medical devices and/or put them into service if they fulfil the requirements prescribed in this Regulation and on condition that they are delivered in a proper manner, correctly installed, used in the intended manner and maintained such that they work as intended and where requirements for safety are fulfilled.

Article 4
Basic requirements.

The devices must fulfil basic requirements as prescribed in Annex I in accompanying document 1 to this Regulation that apply to them, having taken into account their intended use.

Devices that are produced with or from tissue of animal origin, *cf.* paragraph 1 of Article 25, shall also fulfil basic requirements as prescribed in Annex I in accompanying document 1 to this Regulation

and that applied to them, having taking into account their intended use and the requirements prescribed in Annex XIII in accompanying document 1 to this Regulation.

If a relevant risk exists then devices that are also machines in the understanding of Article 2 of Regulation No. 1005/2009, on machines and technical equipment, shall also fulfil basic requirements for health and safety as prescribed in Annex I of that Regulation to the extent that these basic requirements for health and safety are more specialised than the basic requirements prescribed in Annex I in accompanying document 1 to this Regulation.

Article 5

Free movement and devices for specialised use.

It is only authorised to market devices and to put them into service if they carry the CE marking as prescribed in Article 23 that indicates that conformity assessment in accordance with the provisions of Article 11 has been performed.

It is authorised that devices intended for clinical investigation be made available to doctors or to those who have authority for such tests if they fulfil the conditions of Article 21 and of Annex VIII in accompanying document 1 to this Regulation.

It is authorised to place on the market custom-made devices and put them into service if they fulfil the conditions prescribed in Article 11 and in Annex VIII in a company document 1 to this Regulation. Devices in categories IIa, IIb and III shall carry a declaration prescribed in Annex VIII in accompanying document 1 to this Regulation but shall be accessible to specific patients specified in the declaration and identified by name, by initials or by a number code.

Devices according to paragraphs 2 and 3 shall not carry the CE marking.

At trade fairs, exhibitions, at demonstrations and at related events it is authorised to show devices that do not fulfil the conditions of this Regulation on condition that is clearly shown on a prominent sign that it is not possible to market the devices nor to put them into service before they have fulfilled the requirements of the Regulation.

When devices are also covered by other laws and regulations based on directives from the European Union regarding other issues where it is also prescribed that the CE marking should be used, the mark means that the devices also fulfil those laws and regulations.

Should such laws or regulations on the other hand allow the manufacturer to choose during the period of adjustment an arrangement that he/she asks be applied, then the CE marking means that the devices only fulfil the provisions of the regulations applied by the manufacturer. In such circumstances information must be provided about specific aspects of such an arrangement in documents, notifications or instructions that are included with the devices.

Article 6

Reference to standards.

The basic requirements in Article 4 shall be considered fulfilled for devices that are in accordance with the appropriate Icelandic standards that have been adopted on the basis of harmonised European standards and been endorsed by Iceland Standards, *cf.* Act No. 36/2003. Reference to standards is also considered a reference to chapters in the European drugs registry, particularly on chapters about surgical sutures and interaction between medicinal substances and substances in devices that contain medicinal substances, *cf.* Article 6 of the Medicinal Products Act, No. 93/1994, as amended.

Article 7

Safety provisions.

Should it come to light that devices specified in paragraphs 1 and 3 of Article 5 and that have been installed, maintained and used in the proper and intended manner, may threaten the health and/or safety of patients, of users or other parties, then the Medical Director of Health shall take all appropriate temporary measures to take such devices off the market or to ban them from being placed on the market or placed in use. The Medical Director of Health shall inform the EFTA Surveillance Authority of all such measures, specified the reasons for his/her decision and in particular whether nonconformity is a result of:

a) A failure to fulfil the basic requirements prescribed by Article 4.