Pursuant to Article 17 paragraph 2, Article 21 paragraph 6 and Article 36 paragraph 4 of the Law on medical devices* ("Official Gazette of Montenegro", No 24/19), the Ministry of health passed

RULEBOOK

ON BASIC REQUIREMENTS FOR MEDICAL DEVICES*

("Official Gazette of Montenegro", No. 008/24 from 02 February 2024)

Annexes that are the integral part of this Rulebook are available on the following links:

https://eur-lex.europa.eu/eli/reg/2017/745/oj

https://eur-lex.europa.eu/eli/reg/2017/746/oj

I. BASIC PROVISIONS

Article 1

This Rulebook determines in more details the content of the basic requirements for medical devices, conditions and manner of classification of medical devices, as well as conditions for basic requirements for safety and performances of the medical device that is made in a health institution to be used in that particular institution.

Article 2

Terms used in this Rulebook for natural persons in masculine gender include the same terms in feminine gender.

Article 3

Terms used in this Rulebook shall have the following meaning:

1) active implantable medical device means any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure;

2) active medical device means any medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity;

3) Declaration of Conformity of a medical device, (hereinafter: Declaration of conformity) is a document by which the manufacturer confirms that the medical device in question fulfills the basic requirements;

4) implantable medical device means any active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure;

5) in vitro diagnostic medical device means 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:

- concerning a physiological or pathological process or state,
- concerning congenital physical or mental impairments,
- concerning the predisposition to a medical condition or a disease,
- to determine the safety and compatibility with potential recipients,
- to predict treatment response or reactions,
- to define or monitoring therapeutic measures.

Specimen receptacles shall also be deemed to be in vitro diagnostic medical devices. Specimen receptacle means a device, whether of a vacuum-type or not, specifically intended by its manufacturer

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 considered 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;

6) document of conformity of a medical device (hereinafter: document of conformity) is the declaration of conformity, test report, certificate, control certificate or other document confirming the conformity of the medical device with the basic requirements;

7) Clinical Evaluation Report is the documentation on the clinical evaluation;

8) classification of the medical device means a process of determining the risk class of a medical device;

9) medical device (general) means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for diagnostic or therapeutic purposes and which is a software support necessary for its proper use in humans and is used for:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,

- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,

- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,

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

- the control or support of conception, and

- cleaning, disinfection or sterilisation of medical devices.

Medical device does not achieve its principal intended action by pharmacological, immunological or metabolic means, in/on the human body, but which may be assisted in its function by such means;

10) intended purpose means the use for which the device is intended according to the data supplied by the manufacturer on the labelling, in the instructions, or in promotional material;

11) conformity assessment is any activity that determines whether a medical device, i.e. the process of manufacturing a medical device meets the prescribed technical requirements, i.e. the basic requirements of the Law on Medical Devices, in order to determine that the medical device is safe and that it functions in accordance with the intended purpose;

12) manufacturer of a medical device (hereinafter: 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 own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party;

13) authorised representative of the manufacurer of the medical device (hereinafter: authorised representative) means any natural or legal person with permanent or temporary residence in Montenegro who, explicitly designated in writing by the manufacturer that has the headquarters and a manufacturer that does not have the headquarters in Montenegro, acts and conducts the procedures prescribed by the Law on Medical Devices and who is responsible for the safety and performance of a particular medical device in the same manner as the manufacturer of that medical device;

14) quality assurance means a traceable process by which quality is introduced into all stages of the manufacture, including a system of documented monitoring of all starting materials and components and individual manufacturing processes, i.e. technical assessment, which includes all controls in relation to the quality of the medical device (hereinafter: quality management);

15) performance means the ability of a device to achieve its intended purpose as stated by the manufacturer;

16) notified body is a conformity assessment body on which the competent authority of a certain EEA member state or a country with which the European Commission concluded an agreement on mutual recognition of conformity assessment procedures, notified the European Commission to conduct procedures for conformity assessment of a medical device with the requirements of European Union directives, which has its own identification number. The list of approved notified bodies for the field of medical devices may be found European Commission NANDO database;

17) certificate of conformity of a medical device (hereinafter: EC certificate) is a certificate issued by a notified body, i.e. a certificate issued by a designated body that confirms that a medical device or a group of medical devices of a certain manufacturer meet the basic requirements;

18) sponsor of the clinical investigation (hereinafter: sponsor) means a legal or a natural person, which takes responsibility for the initiation, i.e. obtaining approval for the conduct of the clinical investigation, for the management and setting up of the financing of the clinical investigation;

19) placing on the market means the first making available of the medical device with or without compensation, for the purpose of distribution, i.e. use on the Montenegrin market, regardless of whether it is new or fully refurbished, except for medical devices intended for clinical investigations;

20) putting into service means the stage at which a device has been made available to the final user as being ready for use on the Montenegrin market for the first time for its intended purpose;

21) conformity assessment body means a legal person that performs conformity assessment, i.e. activities of technical assessment, including calibration, testing, certification and inspection. Conformity assessment body is a notified body, designated body or authorised body (laboratories, certification bodies, inspection organisations, etc.);

22) CE marking of conformity means a marking by which a manufacturer indicates that a device is in conformity with the basic requirements. CE marking of conformity may be a foreign mark of conformity (CE mark) or another mark of conformity of a medical device, in accordance with the law on technical regulations.

II. GENERAL AND ACTIVE IMPLANTABE MEDICAL DEVICES

Article 4

Basic requirements to be met by the general and active implantable medical devices refer to the following:

1) general requirements for safety and performances;

2) technical documentation;

3) technical documentation on monitoring the medical device on the market;

4) document of conformity;

5) CE mark;

6) necessary documentation for the registration of medical devices and legal persons (manufacturer, authorised representative, importer), information to be submitted for the UDI database and UDI system;

7) requirements to be met by conformity assessment bodies;

8) classification rules;

9) conformity assessment based on the quality management system and assessment of technical documentation;

10) conformity assessment based on type examination;

11) conformity assessment based on the conformity checks and quality assurance and quality assurance of the manufacture;

12) certificates issued by the conformity assessment bodies;

13) procedure for custom-made medical devices;

14) clinical evaluation and post-marketing clinical monitoring;

15) clinical investigations;

16) medical devices without medical purpose.

Article 5

General requirements for safety and performances include general requirements and requirements related to the design and manufacture, i.e. to the performances of the medical device and the information submitted with the medical device.

Article 6

Technical documentation includes the following:

1) description and specification of the medical devices, including variations and articles;

2) information to be submitted by the manufacturer;

3) information on the design and the manufacture;

4) general requirements for safety and performances;

5) benefit-risk analysis and risk management;

6) verification and confirmation of the medical device.

Article 7

Technical documentation on monitoring of the medical device on the market shall include the following:

1) monitoring of the medical device on the market plan;

2) periodic safety report;

3) report on monitoring the medical device on the market.

Article 8

Document of conformity shall contain the following:

1) name and surname, or the name, and unique registration number of the manufacturer, if issued, name and surname, or the name of the authorised representative, address of the permanent residence, i.e. headquarters;

2) statement that the manufacturer bears the sole responsibility for issuing the document of conformity;

3) unique device identification (UDI-DI);

4) name of the medical device, catalog number or other unambiguous reference that enables the identification and traceability of the medical device (if necessary, a photo), as well as its purpose;

5) class of the medical device;

6) a statement that the medical device is compliant, in accordance with the law;

7) references to the common specifications that have been used and in connection with which the certificate of conformity has been issued;

8) name and identification number of the notified body for conformity assessment, description of conducted conformity assessment procedure and the identification of the issued certificate, if applicable;

9) additional information, if necessary;

10) data on the place and date of issuance of the document of conformity, the signatory of the document (name and surname, position), on whose behalf he/she signs the document, signature.

Article 9

General and active implantable medical devices shall be marked with the CE mark in accordance with the regulations governing technical requirements for products and conformity assessment.

Article 10

Manufacturer, authorised representative, or the importer shall submit all information necessary for the registration of medical devices and legal persons, as well as data for the UDI database and UDI system.

Article 11

Basic requirements to be met by the conformity assessment bodies shall include the following:

1) organisation and general requirements;

2) requirements regarding quality management;

3) requirements regarding resources;

4) requirements regarding the procedure.

Article 12

According to the classification rules, medical devices are classified into appropriate classes, depending on the purpose of the medical device and the level of risk for the user.

Article 13

Basic requirements related to the conformity assessment based on the quality management and assessment of the technical documentation shall include the following:

1) quality management system;

2) assessment of the technical documentation;

3) administrative provisions.

Article 14

Basic requirements related to conformity assessment based on type examination include the procedure by which the conformity assessment body determines and confirms that the medical device meets the prescribed conditions.

Article 15

Basic requirements related to conformity assessment based on conformity verification and manufacturing quality assurance include manufacturing quality assurance and the verification of the medical device.

Article 16

Basic requirements related to the certificates issued by the conformity assessment body include the general requirements and the minimum content of the certificate.

Article 17

For general and active implantable custom-made medical devices, the manufacturer or its authorised representative shall make the statement containing the following:

1) name and surname, i.e. the legal name and address of the manufacturer and the manufacturing site of the medical device;

2) name and surname, i.e. the legal name and address of the authorised representative;

3) data enabling the identification of the medical device;

4) statement that the medical device is to be exclusively used by the particular patient or the user;

5) name and surname of the person that dispensed the prescription and the name of the health institution;

6) special features of the medical device, as provided in the prescription;

7) statement that the medical device meets the general requirements for safety and performance, providing also the information on general requirements for safety and performance that are not fully met, with reasons;

8) indication that the medical device contains or includes a substance that is a medicine, including products derived from blood or plasma of human origin or tissue or cells of human or animal origin.

Statement referred to in paragraph 1 of this Article shall be kept for at least ten years for general medical devices, and for at least 15 years for active implantable medical devices after the medical device is placed on the market.

Article 18

The scope of clinical evaluation of a generic and active implantable medical device should be proportionate to the nature, class and purpose of the medical device, as well as the manufacturer's claims in relation to the medical device.

Clinical evaluations shall be updated in the course of post-marketing clinical monitoring.

Article 19

Basic requirements related to clinical investigations of the general and active implantable medical device shall include the following:

1) basic requirements;

2) documentation related to the application for the clinical investigation;

3) other duties of the sponsor of the clinical investigation.

Article 20

General and active implantable medical devices without medical purpose are as follows:

1) Contact lenses or other items intended to be introduced into or onto the eye;

2) Products intended to be totally or partially introduced into the human body through surgically invasive means for the purpose of modifying the anatomy or fixation of body parts with the exception of tattooing products and piercings;

3) Substances, combinations of substances, or items intended to be used for facial or other dermal or mucous membrane filling by subcutaneous, submucous or intradermal injection or other introduction, excluding those for tattooing;

4) Equipment intended to be used to reduce, remove or destroy adipose tissue, such as equipment for liposuction, lipolysis or lipoplasty;

5) High intensity electromagnetic radiation (e.g. infra-red, visible light and ultra-violet) emitting equipment intended for use on the human body, including coherent and non-coherent sources, monochromatic and broad spectrum, such as lasers and intense pulsed light equipment, for skin resurfacing, tattoo or hair removal or other skin treatment;

6) Equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain.

Article 21

Basic requirements referred to in Articles 5 to 20 of this Rulebook are provided in the Annex 1, that is an integral part of this Rulebook.

III. IN VITRO DIAGNOSTIC MEDICAL DEVICES

Article 22

Basic requirements to be met by the in vitro diagnostic medical devices refer to the following:

1) basic requirements for safety and performances;

2) technical documentation;

3) technical documentation on monitoring medical devices on the market;

4) document of conformity;

5) CE mark;

6) information necessary for the registration of medical devices and legal persons (manufacturer, authorised representative, importer), data to be submitted for the UDI database and UDI system;

7) requirements to be met by the conformity assessment bodies;

8) classification bodies;

9) conformity assessment based on the quality management system and assessment of the technical documentation;

10) conformity assessment based on the type examination;

11) conformity assessment based on the conformity verification and quality assurance of the manufacture;

12) certificates issued by the conformity assessment body;

13) assessment of performances, performances studies and post-marketing monitoring of the performances;

14) interventional studies of clinical performances and other studies of performances.

Article 23

Provisions from Articles 5 to 16 of this Rulebook are applied accordingly to the basic requirements referred to in Article 22 paragraph 1 items 1-12 of this Rulebook.

Article 24

Basic requirements related to the assessment of performances, studies of performances and post-marketing monitoring of the performances of in vitro diagnostic medical devices shall include the following:

1) assessment of performances and studies of performances;

2) studies of clinical performances;

3) post-marketing monitoring of the performances.

Article 25

Basic requirements related to interventional studies of clinical performances and other studies of performances of in vitro diagnostic medical device shall include the following:

1) documentation related to the application for interventional studies of clinical performances and other studies of performances which involve risk to the subjects of the studies;

2) other duties of the sponsor.

Article 26

Basic requirements referred to in Article 22 to 25 of this Rulebook are provided in the Annex 2, which is an integral part of this Rulebook.

IV. MEDICAL DEVICES MANUFACTURED IN A HEALTH INSTITUTION

Article 27

Basic requirements to be met by the medical devices made in the health institution intended for use in that health institution relate to the general requirements for safety and performances.

General requirements for safety and performances referred to in the paragraph 1 of this Article shall include the general requirements and requirements related to the design and manufacture, i.e. performances of the medical device and information submitted along with the medical device.

Article 28

Provisions of this Rulebook related to the basic requirements for safety and performances to be met by general, active implantable and in vitro diagnostic medical devices shall be accordingly applied to the medical devices from Article 27 paragraph 1 of this Rulebook.

V. FINAL PROVISION

Article 29

This Rulebook shall enter into force on the 8th day from its publishing in the "Official Gazette of Montenegro".

The following Regulations are transposed into this Rulebook:

- Regulation 2017/745 of the European Parliament and Council of 5 April 2017 on medical devices, amendments to the Directive 2001/83/EC, Regulation (EC) No. 178/2002 and Regulation (EC) No. 1223/2009 and repealing the Directives of the Council 90/385/EEC and 93/42/EEC
- Regulation (EU) 2017/746 of the European Parliament and Council of 5 April 2017 on in vitro diagnostic medical devices and repealing the Directive 98/79/EC and Decision of the Commission 2010/227/EU.

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Podgorica, 30 January 2024

Minister,

dr Vojislav Šimun, m.p.