Consolidated version of the Rulebook on recognition of foreign documents and CE mark and on the registration of a medical device shall include the following regulations:

1. Rulebook on recognition of foreign documents and CE mark and on the registration of a medical device ("Official Gazette of Montenegro", No 085/22 of 02.08.2022.),
2. Rulebook on amendments to the Rulebook on recognition of foreign documents and CE mark and on the registration of medical devices ("Official Gazette of Montenegro", No 126/22 of 18.11.2022.), containing the date of entry into force.

RULEBOOK

ON RECOGNITION OF FOREIGN DOCUMENTS AND CE MARK AND ON THE REGISTRATION OF MEDICAL DEVICES

("Official Gazette of Montenegro", No 085/22 from 02.08.2022., 126/22 of 18.11.2022.)

Subject

Article 1

This Rulebook shall define more detailed conditions, manner and procedure of recognition of foreign documents and CE mark, as well as more detailed content of the application for registration, manner of registration, extension of registration validity period, amendment to the registration data and deletion of a medical devices from the Register of medical devices.

Use of gender-sensitive language

Article 2

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

Definitions of terms

Article 3

Terms used in this Rulebook shall have the following meaning:

1) Declaration of Conformity of a medical device (hereinafter: Declaration of Conformity) is a document by which the manufacturer confirms that the medical device complies with the essential requirements;
2) group of generic medical devices is a set of medical devices that have the same or similar use or common technology that allows them to be classified in a general way without reflecting specific characteristics;

3) notified body for conformity assessment (hereinafter: notified body) is a legal person apointed by the competent ministry for conducting the conformity assesment affairs for a manufacturer's needs;

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

5) category of medical devices is a set of medical devices having a common scope of intended use, or a common technology;

6) user is a healthcare institution, healthcare professional, healthcare associate, or a patient, i.e. a person who uses a medical device;

7) authorised representative of a manufacturer of a medical device (hereinafter: authorised representative) is a legal, or natural person with a seat, or residence in Montenegro who is authorised, in writing by a manufacturer with a seat in Montenegro and a manufacturer that does not have a seat in Montenegrot to act on their behalf and to conduct the procedures prescribed by the law governing the area of medical devices (hereinafter: Law) and who is responsible for safety and performance of a particular medical device in the same way as the manufacturer of that medical device;

8) designated body (authorised body) is a conformity assessment body, i.e. a testing laboratory, a control body and a certification body, to which the state administration body responsible for health affairs has given the authority to perform technical assessment tasks for the needs of the state administration body that conducts conformity assessment;

9) Notified body is a conformity assessment body that the competent authority of a specific member state of the European Economic Area, or a country with which the European Commission has concluded an agreement on mutual recognition of conformity assessment procedures, notified to the European Commission for carrying out procedures for conformity assessment of a medical device with requirements of European Union directives, which has its own identification number. The list of approved notified bodies for the field of medical devices can be found within the "NANDO" database maintained by the European Commission;

10) Manufacturer of a medical device (hereinafter: the manufacturer) is a legal or natural person responsible for its design, manufacture, packaging and labelling before placing it on the market under its own name, whether or not these activities have been performed independently or on behalf by another person;

11) Registration of a medical device is a procedure for the entry of a medical device, for which the conformity assessment has been conducted, in the register of medical devices managed by the Institute for Medicines and Medical Devices (hereinafter: Institute);

12) Free sale certificate is a document proving that a medical device may be placed on the market in the country of the manufacturer, or on the market of a the European Economic Area member state;

13) Certificate of Conformity of a medical device (u daljem tekstu: Certificate of Conformity) is an EC certificate issued by a notified body, or a certificate issued by a designated body certifying that the medical device or a group of medical devices of a particular manufacturer complies with the essential requirements;

14) outer packaging of a medical device is the packaging that holds inner packaging of the medical device;

15) conformity assessment body is a legal person that conducts conformity assessment, i.e. performs technical assessment tasks, including calibration, testing, certification and control. A conformity assessment body is a notified body, a designated body or an authorized body (laboratories, certification bodies, control organizations, etc.);

16) immediate packaging of a medical device is the packaging which the medical device is in direct contact with.

Recognition of foreign documents

Article 4

In accordance with the Law, the Institute recognizes foreign documents and the CE mark in the procedure of registration of a medical device, or at the request of the manufacturer, i.e. its authorized representative.

Conditions for recognition of foreign documents and CE mark

Article 5

Recognition of foreign documents and the CE mark may be done under following conditions:

1) requests from the foreign technical regulations provide at least the same level of protection of safety of human life and health, protection of animals and plants, environmental protection, protection of consumers and other users and property protection, as determined by the requirements of the appropriate technical regulations in Montenegro;

2) requests from the foreign technical regulations which the foreign conformity assessment body must fulfill in order to perform the procedure of conformity assessment for the product provide at least the same degree of fulfillment of the requirements determined for the appropriate technical regulation in Montenegro.

Direct recognition of foreign documents and CE mark

Article 6

Foreign document, i.e. the CE mark is directly recognized in Montenegro if it is issued by a notified body of the European Union, i.e. if it is put on a medical device in accordance with a harmonized technical regulation in the European Union.

Application for recognition of foreign documents and CE mark

Article 7

Application for recognition of foreign documents and CE mark shall particularly contain the following:

1) name and seat of the applicant;
2) stating a foreign document, or a CE mark recognition of which is applied for;
3) name of a foreign technical document based on which foreign document, or a CE mark has been issued;
4) name and address of the conformity assessment body that issued a foreign document;
5) state of the seat of notified body for conformity assessment that issued a foreign document and name of the authority that notified mentioned body;
6) other data important for recognition of foreign document, i.e. CE mark.

Decision on recognition of foreign documents and CE mark

Article 8

Decision on recognition of foreign document, i.e. CE mark shall particularly contain the following:

1) stating a foreign document, i.e. CE mark being recognised;
2) name and seat of the conformity assessment body that issued foreign document;
3) state of the seat of notified body for conformity assessment that issued a foreign document and name of the authority that notified mentioned body;
4) name of a foreign technical document based on which a foreign document has been issued, or a CE mark has been put;
5) name of appropriate technical regulation in Montenegro;
6) validity period of the decision.

Decision on the recognition of a foreign document is valid until the expiration of the period of validity of the foreign document, if that period is specified in the document.

If the validity period is not specified in the foreign document, the decision on the recognition of the foreign document is valid for a maximum of three years from the date of its issuance.

Submission of the application

Article 9

Application for registration, extension of registration validity period, amendment to the registration data and deletion of a medical devices from the Register of medical devices shall be submitted on an appropriate form, as follows:

1) for medical devices of class I - Form 1;
2) for medical devices of class IIa, IIb and III - Form 2;
3) for in vitro diagnostic medical devices - Form 3;
4) for active implantable medical devices (AIMD) - Form 4.

Forms referred to in paragraph 1 of this Article are provided in the Annex that is an integral part of this Rulebook.

Required documentation accompanying the application for registration, or extension of registration validity period

Article 10

An application for registration, or extension of registration validity period shall be accompanied by the following:

1) Number of the Decision on the registration of a manufacturer that does not have a seat, or residence in Montenegro;
2) declaration of conformity;
3) certificate of conformity;
4) insurance policy against harmful consequences that may occur when using the medical device;
5) original instructions for use of the medical device issued by the manufacturer in English, as well as the translation into the Montenegrin and languages that are in official use in Montenegro, confirmed by a medical doctor, or a dentist of appropriate specialty;
6) proposal of the outer packaging and a sticker for Montenegro;
7) other documentation, at the request of the Institute, in accordance with the Law.

Notwithstanding paragraph 1 item 3 of this Article, for registration, i.e. extension of registration validity period of a medical device of class I (general medical devices), other in vitro diagnostic medical devices and in vitro diagnostic medical devices of class A no certificate of conformity shall be submitted.

For manufacturers outside the European Union, in addition to the documentation referred to in paragraph 1 of this Article, a Free sale certificate, or a certificate issued by a designated body ISO 13485 shall be submitted.

Documentation referred to in paragraph 1 of this Article shall be submitted in paper or electronic form, in Montenegrin or English, in the form of originals, or copies signed or verified in accordance with the Law.

When submitting an application for the extension of registration validity period of a medical device, it is not necessary to submit the documentation that was submitted during the registration of that medical device, if the documentation remained unchanged.

In case referred to in paragraph 5 of this Article, the applicant shall submit the manufacturer's statement that the documentation remained unchanged.

Decision on the registration, or extension of registration validity period

Article 11

Decision on the registration, or extension of registration validity period shall contain particularly the following:

1) name and seat of a manufacturer;
2) name and seat of an authorised representative;
3) name of a medical device;
4) group of generic medical devices;
5) category of a medical device;
6) class of a medical device;
7) validity period of the Decision.

Amendment to the registration data of a medical device

Article 12

Application for Amendment to the registration data of a medical device shall be accompanied by the documentation related to the amendment in question.

Entry into force

Article 13

This Rulebook shall enter into force on the eighth day after its publication in the “Official Gazette of Montenegro".

Annexes of this document are available below.