Pursuant to the Article 88 paragraph 7 of the Law on medical devices ("Official Gazette of Montenegro", No 24/19), Ministry of Health passed the

RULEBOOK

ON LABELLING AND CONTENT OF THE INSTRUCTIONS FOR USE FOR A MEDICAL DEVICE

("Official Gazette of Montenegro", No 047/23 from 05 May 2023)

Subject matter

Article 1

This Rulebook prescribes detailed content and manner of labelling of a medical device, as well as the content of the instructions for use for a medical device.

Use of gender sensitive language

Article 2

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

Expressions

Article 3

Expressions used in this Rulebook shall have the following meaning:

1) additional label is a label that is affixed to original outer packaging of a medical device labelled in English, and which contains the information found on the original outer packaging of the medical device in Montenegrin and languages that are in official use in Montenegro, along with other data in accordance with the Law, this Rulebook and essential requirements for medical devices;

2) generic device group means a set of devices having the same or similar intended purposes or a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics;

3) Unique Device Identifier (UDI) is a unique numeric, or alphanumeric code that refers to a medical device, and is comprised of two parts:

- identifier of a medical device; and
- identifier of a manufacturing.

Unique Device Identifier of a medical device provides access to useful and relevant information related to a medical device and makes traceability of a medical device more efficient, enables easier withdrawal of the medical device from the market, suppresses counterfeiting and improves patients' safety. Unique Device Identifier of the medical device is not a substitute for or an addition to prescribed requirements for labelling of a medical device;

4) single-use device means a device that is intended to be used on one individual during a single procedure. A single-use medical device can be used multiple times during one procedure on the same individual or on the same individual for an extended period of time during one procedure. A critical single-use medical device is a single-use medical device intended for use in invasive surgical procedures;

5) label is written, printed or graphic information appearing on the medical device, on the packaging of each component of the medical device or on the packaging of the system or kit and contains information about the authorized representative of the manufacturer and the number of the Decision on the registration of the medical device. A label with information on the number of the Decision on the registration of the medical device in Montenegro can also be found in the Instructions for use;

6) authorized representative of the manufacturer of the medical device (hereinafter: authorized representative) is a legal or natural person with headquarters or residence in Montenegro, authorized in writing by the manufacturer with its headquarters and the manufacturer without its headquarters in Montenegro to act on their behalf and to conduct the procedures prescribed by this Law and which is responsible for safety and performance of a certain medical device in the same manner as the manufacturer of that medical device is;

7) manufacturer of a medical device (hereinafter: manufacturer) is a legal or natural person responsible for the design, manufacturing, packaging and labelling of a medical device before placing a medical device on the market under its own name, regardless of whether it performs these activities independently or they are performed on its behalf by another party;

8) series is a defined amount of starting materials (starting substances or packaging materials) or products made during one manufacturing process, i.e. production or in a series of manufacturing processes, which should therefore be homogeneous. The series shall mean the total amount of the medical device, which was manufactured, i.e. produced from the same initial amount of starting materials during one manufacturing process, i.e. production and one sterilization procedure, and in case of continuous manufacturing, i.e. production, it shall mean the total amount of the medical device that was manufactured, i.e. produced in a certain period;

9) outer packaging of a medical device is the packaging in which the inner packaging of the medical device is placed;

10) inner packaging of a medical device is the packaging which the medical device is in direct contact with;

11) instructions for use for a medical device shall mean information about the medical device provided by the manufacturer necessary for its safe and proper use in relation to the training and knowledge of a potential patient, i.e. the user, as well as information about expected effect of the medical device and precautionary measures to be taken when using the medical device. Instructions for use for the medical device used by healthcare professionals can be submitted by the manufacturer also in electronic form.

Labelling

Article 4

Labelling of the medical device shall be done by stating the information about the medical device on the outer and inner packaging of the medical device.

Information on the outer and inner packaging

Article 5

Following information shall be provided on the outer, or inner packaging of the medical device:

1) information about the manufacturer and authorized representative of the manufacturer (name and headquarters, i.e. name, surname, address of residence);

2) number and date of the Decision on the registration of the medical device;

3) name of the medical device (brand name and/or descriptive name with or without the mark or name of the manufacturer, which is related to the generic device group);

4) CE mark or other mark of conformity of the medical device and identification number of the conformity assessment body that approved the labeling of the medical device with the mark of conformity;

5) required marks, such as: "sterile", "single use", "custom made medical device", "for clinical investigation", "free sample, not for sale", "for performance assessment only", etc.;

6) unique device identifier (UDI-DI), if it has been assigned by the manufacturer;

7) storage conditions, if necessary;

8) purpose, if the purpose of the medical device is not obvious;

9) warning: "Read the instructions before use", if feasible, i.e. generally accepted symbol referring to the instructions for use;

10) wording of the instructions for use, if feasible;

11) series code preceded by the word "SERIES" or serial number, i.e. lot number of the medical device, without abbreviations, i.e. with the use of the abbreviations "Lot" or "SN" if it is not technically possible to provide data without abbreviations, in relation to the size of the packaging of the medical device;

12) date of the manufacturing, if necessary;

13) expiry date, if it has been determined by the manufacturer;

14) necessary warnings and precautionary measures, and

15) other information, in line with essential requirements for medical devices.

Name of the medical device that blind and purblind persons can use independently shall also be indicated in Braille, if feasible.

Excluded from paragraph 1 of this Article, information referred to in items 7, 8, 14 and 15 may be provided in the instructions for use for the medical device, if it is not technically feasible to indicate them on the outer or inner packaging due to the packaging size of the medical device.

Manner of labelling

Article 6

Information on the outer and inner packaging of the medical device shall be indelible, legible, clearly comprehensible and permanent.

Information on the outer packaging of the medical device shall be provided without abbreviations, if feasible.

Labeling of the medical device in multiple languages

Article 7

Information provided on the outer and inner packaging of the medical device in multiple languages shall be identical in all languages, except for the information on the authorized representative of the manufacturer and the number of the Decision on the registration of the medical device in Montenegro.

Expiry date

Article 8

On the outer and inner packaging of the medical device, it shall be clearly stated until when the medical device can be safely used, stating the year and month, and, where relevant, the day, with the note: "Valid until: year and month", "Best before: year and month", etc.

If the information referred to in paragraph 1 of this Article cannot be provided without abbreviations, generally accepted symbols shall be used.

Period of use of the medical device after its first opening, if the medical device can only be used within a certain period after its first opening, shall be indicated on the outer packaging of the medical device.

Expiry date shall be indicated on each unit in a system or a kit, while the outer packaging of a system, or a kit shall contain information on the shortest expiry date of a unit in its composition.

Expiry date of the medical device shall not be indicated for medical devices for which the manufacturer has not determined the expiry date.

Labels

Article 9

Manufacturer, authorized representative of the manufacturer or the wholesaler affixes the label, i.e. an additional label that contains information in accordance with the Law, this Rulebook and the essential requirements for medical devices.

Label, i.e. additional label, is affixed to the original packaging of the medical device in such manner that it does not cover essential data and features (mark of conformity, etc.).

Information about a medical device on the label or additional label shall be indelible, legible, clearly comprehensible and permanent.

Content of the instructions for use for the medical device

Article 10

Instructions for use of the medical device shall contain information referred to in the Article 5 paragraph 1 of this Rulebook, as well as other information important for safe and proper use in accordance with essential requirements for medical devices.

In addition to the data referred to in paragraph 1 of this Article, with the aim of gaining a better understanding, the instructions for use for the medical device may also contain images, symbols or marks, if they are in accordance with essential requirements for medical devices and do not contain advertising elements.

Manufacturer, or authorized representative of the manufacturer, at the request of the organization of blind, purblind or persons having other difficulties in using printed materials, shall provide instructions for the use for the medical device in appropriate form (Braille, capital letters or electronic sound recording - tape, CD, MP3 etc.).

Instructions for use for a medical device in electronic form

Article 11

In the event that a medical device and accompanying equipment can only be used by healthcare professionals, the manufacturer can provide instructions for use for the medical device in question in electronic form, which replaces printed instructions for use for a medical device.

In case referred to in paragraph 1 of this Article, prior to placing the medical device on the market, the manufacturer shall perform a risk assessment and ensure that the instructions for use for the medical device in electronic form do not cause a risk to public health.

Delivery and use method of the instructions for use for the medical device in electronic form shall be mutually determined by the manufacturer, i.e. authorized representative of the manufacturer and the health institution.

In case of non-compliance with the agreement referred to in paragraph 3 of this Article, a health institution may, request delivery of instructions for use for the medical device in printed form.

Entry into force

Article 12

This Rulebook shall enter into force on the eighth day from its publishing in the “Official Gazette of Montenegro”.

No: 5-040/23-928/3

Podgorica, 26 April 2023

Minister,

Dragoslav Šćekić, m.p.