Consolidated version of the Rulebook on more detailed conditions and method of determining the fulfillment of conditions for the retail sale of medical devices shall include the following regulations:

1. Rulebook on more detailed conditions and method of determining the fulfillment of conditions for the retail sale of medical devices ("Official Gazette of Montenegro", No 057/22 from 31 May 2022),

2. Rulebook on amendments to the Rulebook on more detailed conditions and method of determining the fulfillment of conditions for the retail sale of medical devices ("Official Gazette of Montenegro", No 126/22 form 18 November 2022),

3. Rulebook on amendments to the Rulebook on more detailed conditions and method of determining the fulfillment of conditions for the retail sale of medical devices ("Official Gazette of Montenegro", No 099/24 from 15 October 2024), containing the date of entry into force.

RULEBOOK ON MORE DETAILED CONDITIONS AND METHOD OF DETERMINING THE FULFILLMENT OF CONDITIONS FOR THE RETAIL SALE OF MEDICAL DEVICES

("Official Gazette of Montenegro", No 057/22 of 31 May 2022, 126/22 of 18 November 2022, 099/24 from 15 October 2024)

GENERAL PROVISIONS

Subject

Article 1

This Rulebook prescribes more detailed conditions that must be fulfilled by a sale venue in which retail sale of medical devices is carried out (hereinafter: specialized retail store), the method of determining the fulfillment of these conditions, as well as the contents of the retail sale authorization for 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.

Terms

Article 3

Terms used in this Rulebook shall have the following meaning:

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

2) falsified medical device is any device with a false presentation of its identity, or of its source, or its CE marking certificates, or documents relating to CE marking procedures. This definition does not include unintentional quality defects and is without prejudice to infringements of intellectual property rights;

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

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

5) purpose is the use for which a medical device is used in accordance with the data provided by the manufacturer in the labeling, in the instructions for use, or in promotional material;

6) medical device defect is a flaw of a medical device in terms of identity, quality, endurance, reliability, safety, or performance, which includes malfunctions, errors in use, and inadequate labeling.

II. CONDITIONS REGARDING PERSONNEL, PREMISES AND EQUIPMENT

Responsible person

Article 4

In accordance with the Law on medical devices (hereinafter: the Law), specialized retail store shall have an employee (hereinafter: responsible person), who is constantly available and responsible for the following:

1) procurement, receipt, storage, keeping, sale and dispensing of medical devices;

2) keeping records on the type and quantity of medical devices, by individual packages;

3) taking appropriate actions in the process of withdrawal of medical devices from the market;

4) report of suspected falsified medical device or a medical device defect.

Specialized retail store shall conclude a full-time employment contract with a responsible person, in accordance with the Law.

Name and surname of a responsible person and their contact information (phone number and e-mail address) shall be put in a prominent place in a specialized retail store.

Qualification of a responsible person

Article 5

Depending on the level of risk to the user according to which medical devices are classified, a responsible person shall have appropriate qualification as follows:

1) medical devices of class I and IIa - at least completed secondary level of education in relevant field, depending on the purpose of a medical device and at least one year of work experience in the area of the retail sale of medical devices;

2) for medical devices of class I and IIa that are categorized as medical equipment – graduated from the faculty of medicine, dentistry, pharmacy, veterinary medicine, technology, electrical engineering, mechanical engineering, or other relevant faculty, depending of the class and category of a medical device and at least one year of work experience within their profession;

3) medical devices of class IIb and III, in vitro diagnostic medical devices and active implantable medical devices – graduated from the faculty of medicine, dentistry, pharmacy, veterinary medicine, technology electrical engineering, mechanical engineering, or other relevant faculty, depending of the class and category of medical device and at least one year of work experience within their profession.

Notwithstanding paragraph 1 item 3 of this Article, for certain types of medical devices of class IIb, a responsible person may have a completed secondary level of education, if the Institute for Medicines and Medical Devices (hereinafter: the Institute) has determined that the retail sale of a medical device in question may also be carried out in other sale venues, in accordance with the Law.

Employees

Article 6

Depending on the level of risk for the user according to which medical devices are classified and the retail sale volume, a specialized retail store shall have an appropriate number of employees with at least completed secondary level of education in the relevant field.

Employees referred to in paragraph 1 of this Article and a responsible person may be provided with an additional training by a specialized retail store, depending on the class and category, as well as the volume of sale of medical devices.

Type and size of premises

Article 7

Specialized retail store shall have adequate premises for the following:

1) receipt, storage, keeping, sale and dispensing of medical devices;

2) quarantine for storage of defective medical devices, or medical devices withdrawn from the market;

3) sanitary premises;

4) wardrobe.

Area of premises referred to in the paragraph 1 item 1 of this Article shall be adjusted to the type, i.e. class and category of medical devices placed on the market, as well as to the volume of the retail sale and may not have less than 10 m2.

Area of premises referred to in paragraph 1 items 2 and 3 of this Article may not have less than 3 m2.

Specialized retail store where medical devices are prepared for use shall have a special premises for that purpose may not have less than 4 m2.

Premises characteristics

Article 8

Premises referred to in the Article 7 of this Rulebook shall fulfill the following criteria:

1) that is built of solid material, that corresponds to the intended purpose in terms of building and size, that walls, floors and ceilings are flat and smooth and made of material that is not subject to cracking and crumbling, that may be quickly and easily cleaned or washed, and also disinfected;

2) that has adequate lighting, temperature, humidity and ventilation without detrimental direct, or indirect impact on prescribed and safe receipt, storage, holding and dispensing of medical devices;

3) by equipment and devices lay-out it satisfies needs of uninterrupted performance of operational activities, without the risk and possibility of replacing, or mixing different products.

Premises shall be functionally connected so that the uninterrupted work flow and safe storage, holding and dispensing of medical devices are ensured.

Premises for receiving, selling and dispensing medical devices shall be protected from atmospheric conditions.

Premises referred to in paragraph 1 of this Article shall be regularly cleaned, disinfected and controlled depending on its purpose and signs prohibiting smoking, eating and drinking, as well as other types of prohibitions that may affect hygienic conditions shall be put in a prominent place.

Specialized retail store in the other close sale venue

Article 9

In accordance with a Law, specialized retail store may be situated within another closed sale venue.

In case referred to in paragraph 1 of this Article, specialized retail store shall meet the conditions referred to in Article 7 of this Rulebook.

Premises of a specialized retail store referred to in paragraph 1 of this Article shall be physically separated from other premises so that the sale of other products, or provision of services cannot affect the sale of medical devices.

Equipment

Article 10

Specialized retail store shall have adequate equipment as follows:

1) for storage and holding of medical devices, in line with storage conditions determined by a manufacturer;
2) for sale and dispensing of medical devices.

III. DETERMINING THE FULFILLMENT OF CONDITIONS FOR RETAIL SALE OF MEDICAL DEVICES AND THE CONTENTS OF THE RETAIL SALE AUTHORISATION

Determining the fulfillment of conditions

Article 11

Prior to the issuance of a retail sale authorisation, the Institute of Medicines and Medical Devices shall check whether the applicant meets the conditions in terms of personnel, premises and equipment and request other data of importance for issuing the retail sale authorisation, in accordance with the Law and this Rulebook.

Contents of the retail sale authorisation

Article 12

Retail sale authorisation shall contain the following data:

1) logo, name and address of the Institute;

2) legal grounds for issuing the authorisation;

3) number and date of issuing the authorisation;

4) name of a specialized retail store which the authorisation is issued to;

5) seat of a specialized retail store which the authorisation is issued to;

6) address(es) of site(s) of retail sale of medical devices;

7) authorization scope;

8) class of medical device depending on the degree of risk to the user;

9) other data of importance for the retail sale of medical devices.

Final provision

Article 13

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