

INSTRUCTION FOR APPLICANTS FOR THE REGISTRATION OF SPECIALIZED RETAIL STORE/AMENDMENT TO THE REGISTRATION/REMOVAL OF SPECIALIZED RETAIL STORE FROM RETAIL SALE REGISTER OF MEDICAL DEVICES

In accordance with the Law on Medical Devices ("Official Gazette of Montenegro" No 24/19) and Rulebook on more detailed conditions and manner of determining fulfillment of conditions for retail sale of medical devices ("Official Gazette of Montenegro", No. 057/22) the applicant shall submit the following documentation to the Registry office of the Institute for Medicines and Medical Devices:

1. General documents

1. Completed appropriate form for the application for the registration of specialized retail store/amendment to the registration/removal of specialized retail store from the Retail sale register (form available on CInMED portal in the section Medical devices > Retail sale).
2. Procedure for the receipt, storage, and dispensing of medical devices;
3. Protocol/procedure for hygiene maintenance and disinfection of the premises;
4. Procedure related to maintaining the temperature and management of temperature deviations in the storage area of the specialized retail store (if the store sells medical devices for which the manufacturer has not determined the conditions in terms of temperature and air humidity, the procedure in question is not required);
5. Procedure for taking appropriate actions in the process of withdrawing medical devices from the market,
6. Procedure for reporting suspected falsified medical devices, or quality defects;

2. Evidence of fulfillment of personnel requirements:

- a. Responsible person (proof of education and work experience, full-time employment contract, confirmation from the Tax Administration on registration of the employee for pension-disability and health insurance, wedding certificate for employees who changed their last name and appointment decision);
- b. Other employees (proof of education, employment contract, confirmation from the Tax Administration on registration of the employee for pension-disability and health insurance);

3. Evidence of fulfillment of premises requirements:

- a. Study on fulfillment of minimum technical and construction conditions in the premises for performing activities with a drawing of the premises and a legend of rooms with marked measures;

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- b. Sanitary consent for performing the activities in question;
- c. Proof of ownership, lease, or some other manner of disposing of business premises;

4. Evidence of fulfillment of equipment requirements:

Specialised retail store shall have adequate equipment, as follows:

- 1) For storage and preservation of medical devices in accordance with storage conditions determined by the manufacturer – if medical devices sold in the store have determined conditions regarding the temperature and air humidity, certificates of calibration of the equipment used to measure temperature and relative air humidity shall be submitted;
- 2) For sale and dispensing of medical devices – proof of the existence (photos) of shelves and tables on which the storage of medical devices is carried out stored, i.e. their receipt and shipping;
- 3) Evidence of the method of keeping records on the type and quantity of medical devices sold in Montenegro, per individual packages - evidence of the existence of an information system;

5. List of medical devices, or groups of medical devices which the retail authorisation is applied for

6. Other documentation that proves the fulfillment of the conditions prescribed by the Law and secondary legislation adopted for its implementation, at the request of the Institute

II Applicant for the amendment to the registration of specialized retail store shall submit the following documentation:

Completed appropriate form for the application for the registration of specialized retail store/amendment to the registration/removal of specialized retail store from the Retail sale register (form available on CInMED portal in the section Medical devices > Retail sale).

Appropriate proof, i.e. documentation from the item I of this Instruction with regard to the amendment.

III Applicant for the removal of specialized retail store from the Retail sale register shall submit the following documentation:

Completed appropriate form for the application for the registration of specialized retail store/amendment to registration/removal of specialized retail store from the Retail sale register (form available on CInMED portal in the section Medical devices > Retail sale).

Justification of reasons for cessation of performing retail sale of medical devices.

Upon receipt of the application, the invoice shall be issued to the applicant in accordance with applicable price list, based on which payment shall be made with a reference to the invoice number/file number.

Payment of the prescribed fee is a condition for processing the application.