CInMED
Institut za ljekove
i medicinska sredstva Crne Gore
Institute for Medicines and
Medical Devices of Montenegro

INSTRUCTION FOR APPLICANTS FOR REGISTRATION/AMENDMENT TO REGISTRATION/REMOVAL FROM THE WHOLESALE REGISTER OF MEDICAL DEVICES

I In accordance with the Law on Medical Devices *("Official Gazette of Montenegro" No 24/19),* Rulebook on more detailed conditions and manner of determining fulfillment of conditions for wholesale of medical devices *("Official Gazette of Montenegro", No. 132/21*) and Guidelines of Good distribution practice for medical devices, the applicant for registration of the wholesale of medical devices shall submit the following documentation:

1. Completed appropriate Form for registration/amendment to registration/removal from the wholesale register of medical devices (the form is available on CInMED portal, in the vertical part of the portal, in the section Medical Devices/Legislation/Forms/For registration/amendment to registration/removal from the wholesale register of medical devices/Application for registration/amendment to registration/removal from the wholesale register of medical devices

2. Evidence of meeting the requirements regarding **personnel**:
   a. Responsible person (decision on appointment, proof of education and work experience, full-time employment contract, proof of training for the job he/she performs, 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)
   b. Employed persons (proof of education, proof of work experience, proof of training)
   c. Organizational chart of employees

3. Evidence of meeting the requirements regarding **premises:**
   a. study on fulfillment of minimum technical and construction conditions in premises for performing activities with a drawing of premises and a legend of rooms with marked measures
   b. sanitary consent for performing of activities in question
   c. proof of ownership, lease, outsourcing of storage activities, or some other manner of disposing of business premises

4. Evidence of meeting the requirements regarding **equipment**:
   a. proof of disposal of means of transport of medical devices (e.g. proof of ownership of the vehicle, use of the vehicle, outsourcing of transport activities)
   b. proof of the existence of backup power supply (generator, uninterruptible power supply)
   c. proof of the existence of a computerized, or other record keeping system
   d. equipment list and technical data on equipment
   e. proof of the existence of appropriate temperature and humidity monitoring equipment
   f. proof of qualification and/or validation of key equipment
   g. plan for regular (preventive) maintenance of key equipment.

5. Evidence of the implementation of the quality assurance system in line with Guidelines of Good distribution practice of medical devices
   a. Rules of procedure, or other equivalent document
   b. List of QMS documents (procedures, instructions and records)
   c. Evidence of the existence of standard operating procedures (SOPs) on:

   - Procedure for periodic audit of the quality assurance system (review of the management system)
   - Change controls (procedure that defines the process for managing changes that could affect the quality of medical devices and services)
   - Risk management
   - Complaints
   - Qualification of suppliers (approval of suppliers)
   - Buyers qualification (approval of buyers)
   - Training
   - Hygiene
   - Documented information
   - Receipt, storage and delivery of medical devices
   - Action in case of temperature deviations
   - Temperature control in the storage
   - Cleaning procedure
   - Pest control
   - Destruction of medical devices
   - Validation and qualification of equipment
   - handling of returned medical devices
   - Counterfeit medical devices
   - Withdrawal of medical devices from the market
   - Outsourced activities
   - Transport of medical devices
   - Internal checks

   Note: In the process of assessing the compliance of wholesale operation with Guidelines of Good distribution practice of medical devices, the Institute shall retain the right to inspect other SOPs and not only the ones abovementioned. These SOPs shall be submitted to the Institute along with the application for wholesale registration.

6. Other documentation proving the fulfillment of conditions prescribed by the Law and secondary legislation adopted for its implementation, if necessary.

Note: The abovementioned documentation shall be submitted to the Institute when submitting an application for wholesale registration, while other conditions prescribed by the Law, Rulebook and Guidelines for Good distribution practice of medical devices shall be controlled on the spot, when the Commission performs on-the-spot check.

II Applicant for the amendment to the wholesale registration shall submit the following documentation:

1. Completed appropriate Form for registration/amendment to registration/removal from the wholesale register of medical devices (the form is available on CInMED portal, in the vertical part of the portal, in the section Medical Devices/Legislation/Forms/For registration/amendment to registration/removal from the wholesale register of medical devices/Application for registration/amendment to registration/removal from the wholesale register of medical devices
2. Appropriate evidence, i.e. documentation from item I of this Instruction in relation to the amendment.

III Applicant for the removal from the wholesale register of medical devices shall submit the following documentation:

1. Completed appropriate Form for registration/amendment to registration/removal from the wholesale register of medical devices (the form is available on CInMED portal, in the vertical part of the portal, in the section Medical Devices/Legislation/Forms/For registration/amendment to registration/removal from the wholesale register of medical devices/Application for registration/amendment to registration/removal from the wholesale register of medical devices
2. Justification of reasons for cessation of performing wholesale of medical devices.

Upon receipt of the application, the invoice shall be issued to the applicant in accordance with Decision on the payment method and fees for entering, removing and keeping the register of medical devices, manufacturers and legal entities that perform marketing and import of medical devices *("Official Gazette of Montenegro" No 78/2009),* on the basis of 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.