INSTRUCTION FOR APPLICANTS FOR THE REGISTRATION OF MANUFACTURERS OF MEDICAL DEVICES THAT DO NOT THEIR HAVE HEADQUARTERS/TEMPORARY-PERMANENT RESIDENCE IN MONTENEGRO

The applicant shall submit the application and documentation prescribed by this Instruction to the Registry Office of the Institute on working days in the period from 09:00 to 12:00 AM.

If the application and documentation are submitted in electronic form, i.e. in the form of an electronic document in accordance with the Law, they may be submitted on a CD or by e-mail pisarnica@cinmed.me. Please note that in this case, the documents to be signed by the applicant shall be signed with an electronic signature.

The applicant is responsible for the authenticity of the documentation in the procedure of registration/ amendment to registration/removal from the register of manufacturers that do not have headquarters/temporary-permanent residence in Montenegro.

The following documentation shall be submitted for the registration of manufacturers of medical devices that do not have their headquarters/temporary-permanent residence in Montenegro in accordance with the Law on Medical Devices ("Official Gazette of Montenegro", No 24/19):

1. **Letter-headed application (cover letter)** - original in the form of an electronic document (electronically signed) or in paper. The original document in paper form shall be hand-signed and certified with a seal of the applicant.
   Cover letter shall contain the following:
   a. data on the applicant (name and headquarters of the legal person)
   b. subject of the application

2. **Completed Application form for registration/amendment to registration/removal from the register of manufacturers that do not have headquarters/temporary-permanent residence in Montenegro, along with supporting statements** (the form is available on CInMED portal in the section Medical devices – Manufacturing) - original in the form of an electronic document (electronically signed) or in paper. The original document in paper form shall be hand-signed and certified with the seal of the applicant.

3. **Contract or letter of authorisation issued by the foreign manufacturer to the applicant for the products for which the application is submitted** - original in the form of an electronic document (electronically signed) or in paper, in Montenegrin (or in one of the languages that are in official use in Montenegro) or in English language. The original document in paper form shall be hand-signed and certified with the seal of the applicant. If a copy of the original document is submitted in paper form, it shall be notarised in accordance with the Law.

4. **Documentation for responsible persons of the authorized representative for the procedure of registration and vigilance of medical devices** - original in the form of an electronic document (electronically signed) or in paper. If a copy of the original document is submitted in paper form, it shall be notarised in accordance with the Law.
   - evidence on professional qualifications – *a degree in a health-related or technical field, depending on type of a medical device*

- evidence on employment: employment contract and registration confirmation from the Tax Administration.
- evidence on completed education in the field of vigilance of medical devices

Upon receipt of the application, the invoice shall be issued to the applicant in accordance with the Price list published on the portal of the Institute on the basis of which payment shall be made with a reference to the invoice number/file number.

Applications that do not contain documentation prescribed in this Instruction will be rejected as incomplete.

The payment of prescribed fee is a condition for processing the application.