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

INSTRUCTION FOR APPLICANTS FOR REGISTRATION OF MEDICAL DEVICES

The applicant shall, in the previously agreed term, submit to the Institute for Medicines and Medical Devices the application and necessary documentation. The term for submitting applications is scheduled by e-mail: registracijams@cinmed.me

Prior to the registration of a medical device it is necessary to register a manufacturer of a medical device that does not have seat/residence in Montenegro, in accordance with the Instruction for applicants for the registration of manufacturers of medical devices that do not have seat/residence in Montenegro.

In accordance with the *Law on Medical Devices* (*Official Gazette of Montenegro no. 024/19*), and the *Rulebook on recognition of foreign documents and the CE mark and on the registration of medical devices ("Official Gazette of Montenegro", no. 085/22)*, the documentation required for registration of a medical device is listed as follows:

1. Application on the letterhead of the applicant (cover letter)
2. Completed Form for registration of a medical device (in paper, or electronic form in accordance with the law governing the electronic document)
3. Number of the Decision on registration of a manufacturer that does not have seat/residence in Montenegro, or Decision on registration of manufacturers of medical devices that do not have seat/residence in Montenegro (copy of the document)
4. Declaration of Conformity*
5. Accompanying EC certificates, except for *class I medical devices*, *other in vitro* diagnostic medical devices and in vitro diagnostic medical devices of *class A (2017/746/EU)**
6. *Product liability policy insurance* in case of liability for damage caused by the use of medical device in accordance with the Law on insurance
7. Manufacturer's statement to submit technical file of a medical device to the Institute, at the request of the Institute*
8. Original instructions for use of the medical device issued by the manufacturer in English (submitted exclusively in electronic form in PDF format)
9. Translation of the original instructions for use into Montenegrin and languages that are in official use in Montenegro, confirmed by a medical or dental doctor of appropriate specialty
10. Proposal of outer packaging: original packaging (design) and proposed sticker for Montenegro (submitted in electronic form in PDF only).
11. **For manufacturers outside of European Union**: QMS - certificate of quality system ISO 13485*, or the evidence that a medical device in question is marketed in the country of the manufacturer, or in one of the European Economic Area member states (hereinafter: EEA member state) - *Free sale certificate**

Registration holder is required to regularly renew certificates of compliance referred to in the previous section as well as other documents that have a validity period, with the obligation that foreign certificates are original, or notarized copies.

In case that the validity of documents referred to in previous sections is not renewed, or extended, the Institute shall remove the medical device from the Register of medical devices.

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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 prescribed fee is a condition for processing the application.

Within the procedure of assessing formal completeness, the Institute assesses files containing documentation provided in accordance with the Law and given instruction, i.e. original documents, or notarized copies, as stated in this Instruction.

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

The Institute reserves the right to request other documentation from the applicant in the procedure of registration of medical devices in accordance with the Law and secondary legislation adopted for its implementation.

**** Documents must be submitted in paper or electronic form, in Montenegrin or English, the original or photocopy signed or certified in accordance with the law).***