

INSTRUCTION FOR APPLICANTS FOR REGISTRATION OF MEDICAL DEVICES

*In cases of submitting the documentation through the Registry office of the
Institute for Medicines and Medical Devices*

Applicants may submit the application and required documentation to the Institute for Medicines and Medical Devices every working day between 09:00 and 12:00. The documentation is submitted in plastic sheet protectors.

In accordance with the *Law on Medical Devices (Official Gazette of Montenegro No. 024/19 and 84/24)*, 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 headquarters/temporary or permanent 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 in electronic form in PDF only)
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 relevant specialty
10. Proposal of outer packaging: original packaging (design) and proposed sticker for Montenegro (submitted in electronic form in PDF only).
11. As for manufacturers outside of European Union: QMS - certificate of quality system ISO 13485*, or the evidence that a medical device in question is placed on the market in the country of the manufacturer, or in one of the European Economic Area countries (hereinafter: EEA countries) - 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 amount and payment method of fees for performing expert services related to medical devices ("Official Gazette of Montenegro" No 35/23), 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 subordinate legislation adopted for its implementation.

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

NOTE – In case that the applicant submits a request for registration of a medical device that is not in compliance with new regulations: When submitting documentation for the registration of medical devices during transitional periods for the compliance of medical devices with the regulations, the applicants shall observe the following documents:

- Acceptance of the declaration of conformity and EC certificates in the procedures conducted before the Institute for medicines and medical devices during the period of harmonization of national legislation due to the transition from the EU MDD/AIMD Directives to the EU MDR Regulation 2017/745 (*update: 18 June 2025*)
- Acceptance of the declaration of conformity and EC certificate in the procedures conducted before the Institute for medicines and medical devices during the period of transition from the EU Directive IVDD to the Regulation IVDR (EU) 2017/746 (*update: 18 June 2025*)