DOCUMENTATION REQUIRED FOR ISSUANCE OF IMPORT AUTHORISATION FOR MEDICAL DEVICES THAT ARE NOT REGISTERED

An applicant for issuance of import authorisation for medical devices that are not registered shall submit to the Institute for Medicines and Medical Devices the following documentation:

1. **Cover letter:**

   - When submitting an application it is necessary to state **Application for import of medical devices that are not registered** next to the word **Subject** in the header of the letter, then provide the name of a foreign supplier from the application and then list the documentation attached to the application in the text of the letter
   - When submitting additional documentation for already submitted application, it is necessary to state **Additional documentation for the application No…** (provide the number of the application to which additional documentation refers) next to the word **Subject** in the header of the letter and then list additional documentation in the text of a letter

2. **Form of the application**

   Completed form for issuance of import authorization for medical devices that are not registered (available on CInMED portal) shall be submitted in:

   - paper form
   - electronic form

3. **Reasoned proposal / statement**

   A reasoned proposal/ statement of the proposer of an unregistered medical device import (available on CInMED portal)

4. **Required documentation for medical devices from the application:**

- Declaration of conformity and/or certificate of conformity for an unregistered medical device, or a proof that an equivalent safety and performance assessment has been conducted for an unregistered medical device for which a notified body, i.e. a manufacturer with headquarters in an EEA country did not conduct a conformity assessment;
- Free sale certificate, or a certificate issued by an authorized body ISO 13485 for the following medical devices:
  - class I,
  - class Others - In vitro diagnostic medical devices
  - In vitro diagnostic medical devices of class A;
- translation of the manual for an unregistered medical device into Montenegrin and into languages that are in official use in Montenegro, signed by a medical doctor of relevant

specialty for the medical device that a patient is supposed to use independently (on a CD);

Certificate of conformity (EC certificate) for an unregistered medical device shall not be submitted for the following medical devices:

- medical devices of class I,
- Others - In vitro diagnostic medical devices
- In vitro diagnostic medical devices of class A.

5. Pro-forma invoice

Pro-forma invoice from a foreign supplier

6. Other information

Other information, at the request of the Institute, in accordance with the Law.

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.

NOTE – **In case that the applicant submits the application for issuance of import authorisation for an unregistered medical device (emergency import of medical devices that are not in compliance with new regulations):**
When submitting the documentation for emergency import of an unregistered medical device 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)