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

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 for issuance of import authorization for medical devices that are not registered (available on CInMED portal), both in paper and electronic form

3. Justification, or 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 based in an EEA member state did not conduct a conformity assessment;

✓ Free sale certificate, or a certificate issued by an authorized body ISO 13485 for medical devices of class I, Other-In vitro diagnostic medical devices and 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 appropriate specialty for the medical device that a patient is supposed to use independently (on a CD);

Certificate of conformity for an unregistered medical device shall not be submitted for medical devices of class I, Other-In vitro diagnostic medical devices and in vitro diagnostic medical devices of class A.

5. Pro forma invoice from a foreign supplier

6. Other data, 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 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.

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