

REQUIRED DOCUMENTATION FOR ISSUANCE OF EXPERT OPINION ON CLASSIFICATION OF MEDICAL DEVICES WITH REGARD TO A COMBINATION OF A MEDICINE AND MEDICAL DEVICE, MEDICAL DEVICE AND CONSUMER GOODS

This instruction is intended for natural and legal persons applying for expert opinion on classification of medical devices with regard to a combination of a medicine and medical device, medical device and consumer goods.

In accordance with the Law on Medical Devices (*Official Gazette of Montenegro No 24/19*), the Institute of Medicines and Medical devices shall decide on classification of medical devices with regard to a combination of a medicine and medical device, medical device and consumer goods and shall issue other expert opinions.

Applicant for issuance of expert opinion shall submit the following documentation:

1. Completed Application form for the issuance of expert opinion within competences of the Institute for medicines and medical devices (*available on CInMED portal*)
3. Table containing a list of products, along with a name of a manufacturer and country of origin (the list shall be also submitted in electronic form) with completed data, as shown below:

No.	Name of the product
1.	<i>Provide reference number of a product, brand name Brief description of a product's purpose</i>
2.
3.

4. Catalogue of products, or part of it, where product's name may be seen along with its reference number, description and purpose
5. Declaration of Conformity (if applicable for that type of the product)
6. If a product is not a medical device, then it is necessary to submit manufacturer's statement that the product in question is not a medical device, i.e. that it is not complied with directives/regulations relating to medical devices
7. If a product holds a CE mark, then it is necessary to submit copy of the certificate.

Upon receipt of the application, the invoice shall be issued to the applicant on the basis of which payment shall be made with a reference to the invoice number/file number.

Notes

- One application for the issuance of an expert opinion may contain several products, but only if they are manufactured by the same manufacturer.
In case of applying for an expert opinion on the classification of products from various manufacturers, it is necessary to submit an application for products manufactured by each manufacturer separately.
- Payment of the prescribed fee is a condition for processing the application.