

INSTRUCTION FOR SUBMISSION OF APPLICATION FOR EXTENSION OF REGISTRATION/EXTENSION WITH AMENDMENT/AMENDMENT/REMOVAL OF THE DECISION ON REGISTRATION OF A MEDICAL DEVICE FROM THE REGISTER

When applying for *Extension of registration/Extension with amendment/Amendment/Removal from the register of medical devices*, the applicant shall submit the following documentation:

1. Application on the letterhead of the company (cover letter), and in case that new amendments are in question, all of those that are to be made to a renewed Decision on registration shall be listed
2. Completed appropriate form of the application for extension of registration/extension with amendment/amendment/removal from the register of medical devices, stating which amendment type is in question, along with the table No 1 and 2 of given medical devices
3. Copy of the Decision on registration of a medical device that is to be renewed, or amended
4. Applicant shall submit renewed documentation (Declaration of conformity; accompanying EC certificates, etc.) and other documentation required for extension of registration
Note: with regard to submitting renewed documentation, if documents in question ceased to be valid, it is necessary to renew them, while documents with no specified validity date are accepted as valid for up to 5 years from the date of issuance
5. If amendment to the decision is in question, the applicant shall submit all renewed documents that are affected by a new amendment
6. If necessary, the applicant is obliged to submit additional documents, evidence, or justification, at the request of the Institute
7. When submitting instruction manual for medical devices and packaging design, in case the they are too extensive, the applicant may submit the aforementioned documentation in electronic form (on a CD)

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.