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

INSTRUCTION ON THE MANNER OF ARRANGING DOCUMENTATION IN THE FILE FOLDER WHEN APPLYING FOR REGISTRATION OF A MEDICAL DEVICE

When applying for registration of a medical device/entering a medical device into the Register of medical devices, the documentation submitted to the Institute for Medicines and Medical Devices shall be arranged in an exactly prescribed order in an appropriate file folder.

- There are exactly 11 chapters that need to be filled in by an appropriate document.

- If a specific chapter may not be provided with an appropriate document, it is necessary to state that no such document is envisaged for specific medical device(s), i.e. for a specific type of application

- Each chapter shall be numbered (from 1 to 11) and separated from others.

Arranging order is as follows:

1. Application on the letterhead of the applicant
2. Completed appropriate form (Annex: tables 1 and 2)
3. Declaration of Conformity (DoC)
4. EC certificates for medical devices in question
5. EN ISO 13485, etc.
6. Free sale Certificate
7. Insurance policy
8. Statement by the manufacturer to provide technical file for a specific medical device, upon the request of the Institute
9. Evidence on registration of a manufacturer in the Register of the Institute (copy of the Decision on registration of manufacturers of medical devices)
10. Labeling of outer and inner packaging of a medical device
    a. in foreign language
    b. in Montenegrin (labeling proposition)
11. Instruction manual for a medical device:
    a. in foreign language
    b. in Montenegrin (proposal of the manual), with verification - consent of a doctor with proposed translation of the manual

INSTRUCTION ON THE MANNER OF ARRANGING DOCUMENTATION IN THE FILE FOLDER WHEN APPLYING FOR REGISTRATION OF A MEDICAL DEVICE

Note:
Documentation shall be prepared in A4 file folders with hard covers in the same color, which on the side contain following information:

1. Name of the applicant
2. Name of the manufacturer
3. Serial number of the file folder (Vol 1/1)

Information shall be printed on a sticker.