CInMED
Institut za ljekove i
medicinska sredstva Crne Gore

Update: 18 June 2025

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

Pursuant to the Article 120 of EU Regulation 2017/745 with its amendments EU 2020/561 and EU 2023/607, which prescribe a transitional period for the harmonization of medical devices with the regulation, as well as pursuant to the Law on Medical Devices ("Official Gazette of Montenegro", No. 024/19 from 22 April 2019) which prescribes that medical devices may be marketed in Montenegro only on the basis of valid certificates of conformity, the Institute for Medicines and Medical Devices issues the following notice:

1. Medical devices of risk class I that are classified as medical devices of risk class I and in line with requirements of EU Regulation 2017/745 (they do not change the risk class compared to the class that was assigned in accordance with the previously applicable directives), and consequently the inclusion of the Notified Body in their conformity assessment procedure is not required, may be placed on the market and put into use on the territory of Montenegro after 26 May 2021 **only if they comply with the requirements of EU Regulation 2017/745.** If the aforementioned medical devices do not have a Declaration of conformity that complies with EU Regulation 2017/745, they will not be able to be distributed in Montenegro, and the Institute cannot consider Declarations of conformity issued in accordance with Directives 93/42 EEC and 90/385 EEC valid documents.

2. Medical devices of risk class I (class assigned in accordance with previously applicable directives) which, in accordance with EU Regulation 2017/745, change the risk class to a higher one, and for which a Declaration of conformity was issued in accordance with the requirements of Directives 93/42 EEC and 90/ 385 EEC before 26 May 2021, may be placed on the market and put into use in Montenegro **up to 31 December 2028**,

   The applicant shall submit the following documentation to the Institute:

   - A document issued by a Notifying authority confirming that the manufacturer has submitted an official notification for a medical device to the Notified body for conformity assessment and that the Notified body and the manufacturer have signed a written agreement in accordance with Annex VII of the MDR Regulation, as well as for the supervision of medical devices from this agreement (in paper or electronic form, in Montenegrin or English, in the original or a photocopy signed and certified in accordance with the law)

- Statement of the manufacturer that there are no significant changes in the design and purpose of the medical device, that the medical devices do not pose an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of health care

- Document proving that the manufacturer has established a quality management system in accordance with Article 10(9) of the MDR Regulation – quality management system certificate according to ISO 13485 issued by an accredited certification body.

3. Higher risk class medical devices (Is, Im, IIa, IIb, III and AIMD) for which a Declaration of conformity was issued in accordance with the requirements of Directives 93/42 EEC and 90/385 EEC before 26 May 2021, may be placed on the market or put into use on the territory of Montenegro within the time-limits specified in the continuation of this Notice*

***ACCEPTANCE OF EC CERTIFICATES IN THE PROCEDURES CONDUCTED BEFORE THE INSTITUTE FOR MEDICINES AND MEDICAL DEVICES IN THE PERIOD OF HARMONIZATION OF NATIONAL LEGISLATION DUE TO THE TRANSITION FROM THE EU MDD/AIMD DIRECTIVE TO EU MDR REGULATION**

Pursuant to the Law on Medical Devices ("Official Gazette of Montenegro", No. 024/19 from 22 April 2019) and related to the Article 120 of EU Regulation 2017/745/EU with its amendments 2020/561/EU and 2023/607/EU, which prescribe a transitional period for the harmonization of medical devices with EU regulation, and taking into account the corresponding application of the opinion that the Institute obtained from the Ministry of Health of Montenegro (number 1040/22-3829/2 of 23 November 2022), the Institute for Medicines and Medical Devices of Montenegro shall apply new conditions and manner of acceptance of EC certificates - foreign certificates of conformity of medical devices:

If the EC certificate issued by the authorized body in accordance with previously applicable directives was valid on 26 May 2021 and was not subsequently withdrawn, it will remain in force until the following dates, even after the validity date specified on the certificate:

a. **31 December 2027** – for risk class III medical devices, IIb which are implantable (with the exception of sutures, clips, dental fillings, orthodontic appliances, dental restorations, screws, wedges, plates, wires, pins, buckles and connectors), AIMD medical devices.

b. **31 December 2028** – for risk class IIb medical devices which are not included in the item a., risk class IIa and risk class I that are placed on the market in sterile condition, or have a measuring function.

- **In order for medical devices to be placed on the market and put in use on the territory of Montenegro by December 2027 and 2028, the following conditions must be met:**

  - that medical devices still comply with directives 90/385/EEC and 93/42/EEC;
  - that there are no significant changes in the design and purpose of the medical device;
  - that the medical device does not pose an unacceptable risk to health or safety of patients, users or other persons or to other aspects of health care;
  - that the manufacturer established a quality management system in accordance with Article 10(9) MDR no later than 26 May, 2024;

- that the manufacturer submitted an official notification to the authorized conformity assessment body no later than 26 May 2024;
- that the notified body and the manufacturer signed a written agreement in accordance with Annex VII of the MDR, no later than 26 September, 2024;

- **<u>Applicant shall submit the following documentation to the Institute:</u>**

a. EC certificate, which expired but was valid on 26 May 2021 and which was not subsequently withdrawn (in paper or electronic form, in Montenegrin or in English, in the original or a copy signed or certified in accordance with the law).

b. Statement of the manufacturer of the medical device confirming that there are no significant changes in the design and purpose of the medical device and that the medical device does not pose an unacceptable risk to health or safety of the patient, user or other persons, or to other aspects of health care (in paper or electronic form, on in Montenegrin or in English, in the original or a copy signed or certified in accordance with the law).

c. Document issued by the Notifying authority confirming that the manufacturer of the medical device submitted an official notification to the authorised conformity assessment body and that the Notified body and the manufacturer signed a written agreement in accordance with Annex VII of the MDR Regulation, as well as for the supervision of medical devices from this agreement (in paper or electronic form, in Montenegrin or in English, in the original or a photocopy signed or certified in accordance with the law);

d. Document proving that the manufacturer has established a quality management system in accordance with Article 10(9) of the MDR Regulation - a quality management system certificate according to ISO 13485 issued by an accredited certification body.