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Institut za ljekove i
medicinska sredstva Crne Gore

# MANNER OF RECOGNIZING 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 received by the Institute 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 recognizing EC certificates - foreign certificates of conformity of medical devices:

1. **WHEN THE PROCEDURE OF COMPLIANCE OF MEDICAL DEVICES WITH EU REGULATION 2017/745 HAS BEEN INITIATED BY SUBMISSION OF DOCUMENTATION BY THE MANUFACTURER TO THE NOTIFIED BODY, THE PROCEDURE FOR RECOGNIZING EC CERTIFICATE IS AS FOLLOWS:**

If the EC certificate issued by the authorized body in accordance with previously valid directives was valid on 26 May 2021 and was not subsequently withdrawn, it will remain in force until the following dates, even after the validity date specified on the certificate: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 establishes a quality management system in accordance with Article 10(9) MDR no later than 26 May, 2024;

- that the manufacturer submits an official application to the authorized conformity assessment body no later than 26 May 2024;
- that the designated body and the manufacturer sign a written agreement in accordance with Annex VII of the MDR, no later than 26 September, 2024;

- **Applicant shall submit the following documentation to the Institute:**

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 Notified body confirming that the manufacturer of the medical device submitted an official application to the authorised conformity assessment body and that the designated 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.

- **2. WHEN THE PROCEDURE OF COMPLIANCE OF MEDICAL DEVICES WITH REGULATION 2017/745 HAS NOT BEEN INITIATED BY SUBMISSION OF DOCUMENTATION BY THE MANUFACTURER TO THE NOTIFIED BODY, THE PROCEDURE FOR RECOGNIZING THE EC CERTIFICATE IS AS FOLLOWS:**

- If the EC certificate was issued by an authorized body in accordance with the previously valid directives 90/385/EEC and 93/42/EEC from 25 May 2017 and was valid on 26 May 2021 when EU Regulation 2017/745 began to be applied, and which was not subsequently withdrawn and the manufacturer did not submit an official application to the authorized body for conformity assessment, i.e. the manufacturer and the authorized body did not sign a written agreement in accordance with Annex VII of the EU Regulation, the Institute shall issue decisions for extending the registration of medical devices with a period of validity **up to 26 May 2024.**

- **Applicant shall submit the following documentation to the Institute:**

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).