CInMED

Institute for Medicines and Medical Devices of Montenegro

**ACCEPTANCE OF THE DECLARATION OF CONFORMITY 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**

Pursuant to the Article 120 of EU Regulation 2017/745 with its amendments EU 2020/56 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 sold 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 valid 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 valid 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**, but only provided 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, which is proven by attaching the manufacturer's statement when submitting the documentation to the Institute. If the Declaration of conformity was issued after 26 May 2021, in addition to the Statement that there have been no changes in the design and purpose of the medical device, a Statement on the reasons for issuing a new Declaration of conformity shall be attached. Statements in question shall be submitted in paper or electronic form, in Montenegrin or in English, in the original or a copy signed or certified in accordance with the law.

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



T: + 382 (0) 20 310 280
+ 382 (0) 20 310 281
+ 382 (0) 20 310 580

M: info@cinmed.me
W: www.cinmed.me
A: Bulevar Ivana Crnojevića 64a, 81000 Podgorica, Crna Gora

PIB: 02739658
ŽR: 520-3603-33 - Hipotekarna Banka
520-3603-33 – NLB Banka

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 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 " which was published on the portal of the Institute for Medicines and Medical Devices.