CInMED

Institute for Medicines and
Medical Devices of Montenegro

Acceptance of the Declaration of conformity and EC certificate in the procedures conducted before the Institute for medicines and medical devices during the period of transition from the EU Directive IVDD to the Regulation IVDR (EU) 2017/746

In accordance with the Law on medical devices ("Official Gazette of Montenegro", No 24/19) prescribing that the medical devices may be marketed in Montenegro only on the basis of valid certificates of conformity, and regarding Article 110 (3) of the Regulation EU 2017/746 (with amendments No EU 2022/112 and EU 2023/607), which defines the transitional period for compliance of "in vitro" diagnostic medical devices, and taking into account the opinion that the Institute obtained from the Ministry of health of Montenegro (No 1-040/23-4279/2 from 14 December 2023), the Institute for medicines and medical devices of Montenegro shall apply new conditions regarding the manner of acceptance of declarations of conformity and EC certificates – foreign certificates of conformity of medical devices:

1. *,,In vitro"* diagnostic medical devices of the risk class ,,*other IVDs*" – in accordance with the requirements of the Directive 98/79 EC, that are classified as medical devices of ,,class A" – in accordance with the requirements of the Regulation EU 2017/746, i.e. for which the procedure of conformity assessment, i.e. engaging the Notified body is not required by the Regulation, after 26 May 2022 may be placed onto the market or put to use only with the condition that they meet the requirements defined in the Regulation EU 2017/746.

- After 26 May 2022, the Declaration of conformity issued in accordance with the requirements of the Directive 98/79 EC may not be considered a valid document, and such Declaration will not be accepted in the procedures conducted before the Institute of medicines and medical devices. The Declaration of Conformity must be in line with the requirements of the Regulation EU 2017/746.

2. ,,In vitro" diagnostic medical devices of the risk class ,,other IVDs" – in accordance with the requirements of the Directive 98/79 EC, which in line with the requirements of the Regulation EU 2017/746 change the risk class to the higher one (*A sterile, B, C, D*), for which the Declaration of conformity was issued in accordance with the requirements of the Directive 98/79 EC before 26 May 2022 may be placed onto the market or put to use provided that there are no significant changes regarding the design and purpose of ,,In vitro" diagnostic medical devices as follows :

- other IVDs moving to class D – up to 26 May 2025

- other IVDs moving to class C – up to 26 May 2026

- other IVDs moving to class B – up to 26 May 2027

- other IVDs moving to class A sterile – up to 26 May 2027

Note: In order for the Declaration of Conformity from item 2 of this Note to be accepted in the proceedings conducted before the Institute, it is necessary for the applicant to submit a Manufacturer's statement

***stating that there are no significant changes regarding the design and purpose of the medical device, that the medical device does not represent an unacceptable risk to the health or safety of patients, users or other persons or to other aspects of health care. The applicant must also submit a Manufacturer's statement stating the risk class that the other IVD moves to. If the Declaration of conformity was issued after 26 May 2022, it is necessary to submit a Manufacturer's statement stating the reasons for issuing a new Declaration of conformity*.**

3. *„In vitro“* diagnostic medical devices of the higher risk class *„List A, List B, Self-testing“* that still meet the requirements of the Directive 98/79 EC (included by valid EC certificate issued in line with IVDD before 26 May 2022, i.e. IVDs stated in the Annex II IVDD and IVD for self-testing), which in accordance with the requirements of the Regulation EU 2017/746 change the risk class to B, C, D for which the Declaration of conformity was issued in line with the requirements of the Directive 98/79 EC, before 26 May 2022, may be placed onto the market and put to use provided that there are no significant changes regarding the design and purpose of an "In vitro" diagnostic medical device up to **26 May 2025.**

Note: In order for the Declaration of Conformity from item 3 of this Note to be accepted in the proceedings conducted before the Institute, it is necessary for the applicant to submit a Manufacturer's statement stating that there are no significant changes regarding the design and purpose of the medical device, that the medical device does not represent an unacceptable risk to the health or safety of patients, users or other persons or to other aspects of health care, as well as the reasons for issuance of new Declaration of conformity, in case that it was issued after 26 May 2022.

4. If the EC certificate that was issued by the authorised body in line with the directive 98/79 EC from 26 May 2017 expired, but was valid on 26 May 2022 and was not subsequently recalled, the Institute will issue the Decision on registration/Extension of registration with the validity period up to **26 May 2025.**

- The applicant shall submit the following documentation to the Institute

a. EC certificate – which expired but was valid on 26 May 2022 and which was not subsequently recalled (original in electronic and paper form/notarised copy).

b. Statement stating that there are no significant changes regarding the design and purpose of the medical device, that the medical device does not represent an unacceptable risk to the health or safety of patients, users or other persons or to other aspects of health care (original in electronic or paper form/notarised copy).