Update: 18 June 2025

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 and 84/24) 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, EU 2023/607 and EU 2024/1860), 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 a 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 in the following manner:

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+ 382 (0) 20 310 281
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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
530-166587-93 – NLB banka

2.1 *Other IVDs* moving to class D

Procedure II – the manufacturer possesses ISO certificate and written agreement

The applicant shall submit the following documentation to the Institute:

a) A statement from the manufacturer that there are no significant changes of the design and purpose of in-vitro diagnostic device, that in-vitro diagnostic device does not pose an unacceptable risk to the health or safety of patients, users or other persons or to other aspects of healthcare (original in electronic or paper form/notarized copy);
b) A statement from the manufacturer that other IVD device moves to class D (original in electronic or paper form/notarized copy);
c) ISO certificate 13485 (original in electronic or paper form/notarized copy);
d) 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 an agreement in accordance with Annex VII of the MDR Regulation - information on the responsibility for conducting market surveillance for in vitro diagnostic device that is the subject of registration must be provided (original in electronic or paper form/notarized copy).

The Decision is issued until 31 December 2027.

2.2 *Other IVDs* moving to class C

Procedure I – the manufacturer does not possess ISO certificate and written agreement

The applicant shall submit the following documentation to the Institute:

a) A statement from the manufacturer that there are no significant changes of the design and purpose of in-vitro diagnostic device, that in-vitro diagnostic device does not pose an unacceptable risk to the health or safety of patients, users or other persons or to other aspects of healthcare (original in electronic or paper form/notarized copy);
b) A statement from the manufacturer that other IVD device moves to class C (original in electronic or paper form/notarized copy);

The Decision is issued until 26 May 2026

Procedure II – the manufacturer possesses ISO certificate and written agreement

The applicant shall submit the following documentation to the Institute:

a) A statement from the manufacturer that there are no significant changes of the design and purpose of in-vitro diagnostic device, that in-vitro diagnostic device does not pose an unacceptable risk to the health or safety of patients, users or other persons or to other aspects of healthcare (original in electronic or paper form/notarized copy);
b) A statement from the manufacturer that other IVD device moves to class C (original in electronic or paper form/notarized copy)
c) ISO certificate 13485 (original in electronic or paper form/notarized copy)

d) 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 an agreement in accordance with Annex VII of the MDR Regulation - information on the responsibility for conducting market surveillance for in vitro diagnostic device that is the subject of registration must be provided (original in electronic or paper form/notarized copy).

The Decision is issued until 31 December 2028.

2.3 *Other IVDs* moving to class B

Procedure I – the manufacturer does not possess ISO certificate and written agreement

The applicant shall submit the following documentation to the Institute:

a) A statement from the manufacturer that there are no significant changes of the design and purpose of in-vitro diagnostic device, that in-vitro diagnostic device does not pose an unacceptable risk to the health or safety of patients, users or other persons or to other aspects of healthcare (original in electronic or paper form/notarized copy);
b) A statement from the manufacturer that other IVD device moves to class B (original in electronic or paper form/notarized copy)

The Decision is issued until 26 May 2027

Procedure II – the manufacturer possesses ISO certificate and written agreement

The applicant shall submit the following documentation to the Institute:

a) A statement from the manufacturer that there are no significant changes of the design and purpose of in-vitro diagnostic device, that in-vitro diagnostic device does not pose an unacceptable risk to the health or safety of patients, users or other persons or to other aspects of healthcare (original in electronic or paper form/notarized copy);
b) A statement from the manufacturer that other IVD device moves to class B (original in electronic or paper form/notarized copy)
c) ISO certificate 13485 (original in electronic or paper form/notarized copy)
d) 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 an agreement in accordance with Annex VII of the MDR Regulation - information on the responsibility for conducting market surveillance for in vitro diagnostic device that is the subject of registration must be provided (original in electronic or paper form/notarized copy)

The Decision is issued until 31 December 2029

2.4 *Other IVDs* moving to class A sterile

Procedure I – the manufacturer does not possess ISO certificate and written agreement

The applicant shall submit the following documentation to the Institute:

a) A statement from the manufacturer that there are no significant changes of the design and purpose of in-vitro diagnostic device, that in-vitro diagnostic device does not pose an unacceptable risk to the health or safety of patients, users or other persons or to other aspects of healthcare (original in electronic or paper form/notarized copy);
b) A statement from the manufacturer that other IVD device moves to class A sterile (original in electronic or paper form/notarized copy)

The Decision is issued until 26 May 2027

Procedure II – the manufacturer possesses ISO certificate and written agreement

The applicant shall submit the following documentation to the Institute:

a) A statement from the manufacturer that there are no significant changes of the design and purpose of in-vitro diagnostic device, that in-vitro diagnostic device does not pose an unacceptable risk to the health or safety of patients, users or other persons or to other aspects of healthcare (original in electronic or paper form/notarized copy);
b) A statement from the manufacturer that other IVD device moves to class A sterile (original in electronic or paper form/notarized copy)
c) ISO certificate 13485 (original in electronic or paper form/notarized copy)
d) 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 an agreement in accordance with Annex VII of the MDR Regulation - information on the responsibility for conducting market surveillance for in vitro diagnostic device that is the subject of registration must be provided (original in electronic or paper form/notarized copy)

The Decision is issued until 31 December 2029

3. 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 withdrawn, in vitro diagnostic medical device may be marketed up to **31 December 2027** at latest.

3.1 PROCEDURE I – when the procedure of harmonization with IVDR in the NB has been initiated

The applicant shall submit the following documentation to the Institute:

a) EC certificate – which has expired but was valid on 26 May 2022 and which was not subsequently withdrawn (original in electronic or paper form/notarized copy)
b) A statement from the manufacturer that there are no significant changes of the design and purpose of in-vitro diagnostic device, that in-vitro diagnostic device does not pose an

unacceptable risk to the health or safety of patients, users or other persons or to other aspects of healthcare (original in electronic or paper form/notarized copy);

c) ISO certificate 13485 (original in electronic or paper form/notarized copy)
d) 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 an agreement in accordance with Annex VII of the MDR Regulation - information on the responsibility for conducting market surveillance for in vitro diagnostic device that is the subject of registration must be provided (original in electronic or paper form/notarized copy)

The Decision is issued until 31 December 2027

3.2 PROCEDURE II – when the procedure of harmonization with IVDR in the NB has not been initiated

The applicant shall submit the following documentation to the Institute:

a) EC certificate – which has expired but was valid on 26 May 2022 and which was not subsequently withdrawn (original in electronic or paper form/notarized copy)
b) A statement from the manufacturer that there are no significant changes of the design and purpose of in-vitro diagnostic device, that in-vitro diagnostic device does not pose an unacceptable risk to the health or safety of patients, users or other persons or to other aspects of healthcare (original in electronic or paper form/notarized copy).

The Decision is issued until 31 December 2025.