EU Declaration of Conformity

as per Annex IV of the Regulation EU 2017/746 on in-vitro diagnostic medical devices

Manufacturer: Roche Diagnostics GmbH
Address: Sandhofer Strasse 116
68305 Mannheim
Germany

Single Registration Number: DE-MF-000006260

Roche Diagnostics GmbH declares, under the sole responsibility, that the product/the product line

Product Name	**Cat. No.**	**Basic UDI-DI**
CA 72-4 CalSet	09175130190	7613336011409V

Intended Use:
CA 72-4 CalSet is used for calibrating the quantitative Elecsys CA 72-4 assay on cobas e immunoassay analyzers.

Product Name	**Cat. No.**	**Basic UDI-DI**
Elecsys CA 72-4	09005692190	761333601138AA
Elecsys CA 72-4	09005706190	761333601139AC
Elecsys CA 72-4	09005706214	761333602923BC
Elecsys CA 72-4	09744525190	761333602852BE

Intended Use:
Immunoassay for the in vitro quantitative determination of CA 72-4 in human serum and plasma. The assay in particular serves as an aid in the therapeutic monitoring of carcinomas of the stomach and ovaries.
The electrochemiluminescence immunoassay “ECLIA” is intended for use on cobas e immunoassay analyzers.

Risk Class: ☐ *A* ☐ *B* ☒ *C* ☐ *D*

Conformity Route:
☐ *Self-Declaration of Conformity (Class A)*
☐ *Self-Declaration of Conformity after Notified Body involvement for sterile manufacturing conditions acc. Art. 48 (10) (Class A sterile)*
☒ *Technical Documentation Assessment Class B/C – Annex IX*
☐ *Technical Documentation Assessment Class D – Annex IX*
☐ *Technical Documentation Assessment Class B/C/D for Self-Testing – Annex IX*
☐ *Technical Documentation Assessment Class B/C/D for Near-Patient Testing – Annex IX*
☐ *Technical Documentation Assessment Class C/D for Companion Diagnostics – Annex IX*

Digitally signed by Lazari Cristina
Date: 2024.11.18 15:54:11 EET
Reason: MoldSign Signature
Location: Moldova

Roche Diagnostics GmbH; Sandhofer Straße 116; D-68305 Mannheim; Telefon +49-621-759-0; Telefax +49-621-759-2890

Certificates:	☒ *EU QM Certificate No.: V12 010283 0639*
	☐ *EU Technical Documentation Assessment Certificate No. (Class D, Near-Patient Testing, Self-Testing and Companion Diagnostics):*
Other:	☐ *Common Specifications:*
Notified Body (NB) Name:	*TÜV Süd Product Service GmbH*
NB Address:	*Ridlerstraße 65* *80339 Munich* *Germany*
NB Ident. No.:	*0123*

to which this declaration relates fulfils the requirements of Regulation EU 2017/746 on in-vitro diagnostic medical devices.

Mannheim, 22 March 2024

Roche Diagnostics GmbH

i.V./*on behalf of the company*

DocuSigned by:
Bernd Röttinger
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Dr. Bernd Röttinger
Head of Pre-Market Quality Point of Care

ppa./*on behalf of the company*

DocuSigned by:
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