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
Elecsys Vitamin B12 II	07028121190	7613336004029V
Elecsys Vitamin B12 II	07028121214	761333602062A9

Intended Use:
Binding assay for the in vitro quantitative determination of vitamin B12 in human serum and plasma.
The electrochemiluminescence immunoassay "ECLIA" is intended for use on cobas e immunoassay analyzers.

Product Name	Cat. No.	Basic UDI-DI
Elecsys Vitamin B12 II	07212771190	761333600436AE

Intended Use:
Binding assay for the in vitro quantitative determination of vitamin B12 in human serum and plasma.
The **e**lectro**c**hemi**l**uminescence **i**mmuno**a**ssay "ECLIA" is intended for use on Elecsys and cobas e immunoassay analyzers.

Product Name	Cat. No.	Basic UDI-DI
Vitamin B12 II CalSet	07212780190	761333600437AG

Intended Use:
Vitamin B12 II CalSet is used for calibrating the quantitative Elecsys Vitamin B12 II assay 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*

Digitally signed by Lazari Cristina
Date: 2023.06.19 16:32:41 EEST
Reason: MoldSign Signature
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Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 3962 - Geschäftsführung: Claus Haberda; Clemens Schmid - Aufsichtsratsvorsitzender: Dr. Thomas Schinecker

	☐ *Technical Documentation Assessment Class C/D for Companion Diagnostics – Annex IX*
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: *NB Address:* *NB Ident. No.:*	*TÜV Süd Product Service GmbH* *Ridlerstraße 65* *80339 Munich* *Germany* *0123*

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

Mannheim, 7 December 2022

Roche Diagnostics GmbH

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

DocuSigned by:
Christina Schmid
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Dr. Christina Schmid
Head of Pre-Market Quality Core Lab

ppa./*on behalf of the company*

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