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 Cyclosporine	05889014190	761333600370A9

Intended Use:
Immunoassay for the in vitro quantitative determination of cyclosporine in human whole blood. The assay is used as an aid in the management of heart, liver, kidney, lung and bone marrow transplant patients receiving cyclosporine therapy.
The electrochemiluminescence immunoassay "ECLIA" is intended for use on Elecsys and cobas e immunoassay analyzers.

Product Name	Cat. No.	Basic UDI-DI
Elecsys Cyclosporine	07251246190	761333600440A5

Intended Use:
Immunoassay for the in vitro quantitative determination of cyclosporine in human whole blood. The assay is used as an aid in the management of heart, liver, kidney, lung and bone marrow transplant patients receiving cyclosporine therapy.
The electrochemiluminescence immunoassay "ECLIA" is intended for use on cobas e immunoassay analyzers.

Product Name	Cat. No.	Basic UDI-DI
Cyclosporine CalSet	05889022190	761333600371AB

Intended Use:
Cyclosporine CalSet is used for calibrating the quantitative Elecsys Cyclosporine assay on cobas e immunoassay analyzers.

Digitally signed by Lazari Cristina
Date: 2024.10.15 11:58:19 EEST
Reason: MoldSign Signature
Location: Moldova

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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*
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, 15 March 2023

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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