

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 Tacrolimus	05889057190	761333600372AD

Intended Use:

Immunoassay for the in vitro quantitative determination of tacrolimus in human whole blood. The assay is used as an aid in the management of heart, liver and kidney transplant patients receiving tacrolimus therapy. The electrochemiluminescence immunoassay “ECLIA” is intended for use on Elecsys and cobas e immunoassay analyzers.

Product Name	Cat. No.	Basic UDI-DI
Elecsys Tacrolimus	07251254190	761333600441A7

Intended Use:

Immunoassay for the in vitro quantitative determination of tacrolimus in human whole blood. The assay is used as an aid in the management of heart, liver and kidney transplant patients receiving tacrolimus therapy. The electrochemiluminescence immunoassay “ECLIA” is intended for use on cobas e immunoassay analyzers.

Product Name	Cat. No.	Basic UDI-DI
Tacrolimus CalSet	05889065190	761333600373AF

Intended Use:

Tacrolimus CalSet is used for calibrating the quantitative Elecsys Tacrolimus 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
☐ 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:

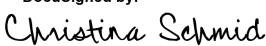
Notified Body (NB) Name: TÜV Süd Product Service GmbH
 NB Address: Ridlerstraße 65
 80339 Munich
 Germany
 NB Ident. No.: 0123

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

Mannheim, 15 March 2023

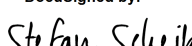
Roche Diagnostics GmbH

i.V./on behalf of the company

DocuSigned by:

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

ppa./on behalf of the company

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Dr. Stefan Scheib
 Global Head of Regulatory Affairs, Core Lab

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