

EG-Konformitätserklärung/EC Declaration of Conformity

gemäß Anhang III der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998
as per Annex III of Directive 98/79/EC of the European Parliament and Council of 27 October 1998

Hersteller/Manufacturer: Roche Diagnostics GmbH

Adresse/Address: Sandhofer Strasse 116
D-68305 Mannheim

Die Roche Diagnostics GmbH erklärt, dass das Produkt/die Produktfamilie
Roche Diagnostics GmbH declares that the product/the product line

Produktname/Product name: **Elecsys Tacrolimus**

Art.-Nr./Cat. No.: **05889057190**

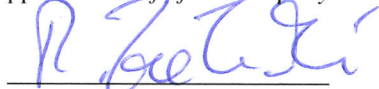
Beschreibung/Description: Immunologischer in vitro Test zur quantitativen Bestimmung von Tacrolimus in humanem Vollblut. Dieser Test dient als Hilfsmittel bei der Behandlung von Herz-, Leber- und Nieren-transplantierten Patienten unter Tacrolimustherapie.
Der ElektroChemiLumineszenz ImmunoAssay "ECLIA" ist zur Durchführung an Elecsys und **cobas e** Immunoassay-Systemen vorgesehen.
*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.*

auf das/die sich diese Erklärung bezieht, den Forderungen der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998 über In-vitro-Diagnostica (bzw. seine Umsetzung in nationales Recht der Mitgliedsstaaten in welchen das Produkt vermarktet werden soll) entspricht.
to which this declaration relates fulfils the requirements of Directive 98/79/EC of the European Parliament and Council of 27 October 1998 on in-vitro diagnostic medical devices (and its relevant transposition into the national laws of the Member States in which the device is intended to be placed on the market).

Mannheim, 11 September 2017

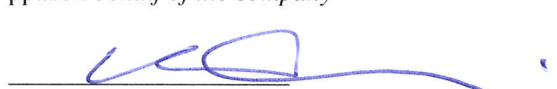
Roche Diagnostics GmbH

ppa./on behalf of the company



Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions

ppa./on behalf of the company



Dr. Peter Martin
Senior Director Global Regulatory Affairs
Centralised and Point of Care Solutions

Kontaktadresse/Contact address: Roche Diagnostics GmbH
Abt./Dept. Global Regulatory Affairs
Sandhofer Strasse 116
D-68305 Mannheim

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Die Roche Diagnostics GmbH erklärt, dass das Produkt/die Produktfamilie
Roche Diagnostics GmbH declares that the product/the product line

Produktname/Product name: **Elecsys Everolimus**

Art.-Nr./Cat. No.: **06633188190**

Beschreibung/Description: Immunologischer In-vitro-Test zur quantitativen Bestimmung von Everolimus in humanem Vollblut. Dieser Test dient als Hilfsmittel bei der Behandlung von Nieren-, Leber- und Herz-transplantierten Patienten unter Everolimustherapie.
Der ElektroChemiLumineszenz ImmunoAssay "ECLIA" ist zur Durchführung an Elecsys und **cobas e** Immunoassay-Systemen vorgesehen.
Immunoassay for the in vitro quantitative determination of everolimus in human whole blood. The assay is used as an aid in the management of kidney, liver and heart transplant patients receiving everolimus therapy.
*The electrochemiluminescence immunoassay "ECLIA" is intended for use on Elecsys and **cobas e** immunoassay analyzers.*

auf das/die sich diese Erklärung bezieht, den Forderungen der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998 über In-vitro-Diagnostica (bzw. seine Umsetzung in nationales Recht der Mitgliedsstaaten in welchen das Produkt vermarktet werden soll) entspricht.

to which this declaration relates fulfils the requirements of Directive 98/79/EC of the European Parliament and Council of 27 October 1998 on in-vitro diagnostic medical devices (and its relevant transposition into the national laws of the Member States in which the device is intended to be placed on the market).

Mannheim, 2 May 2018

Roche Diagnostics GmbH

ppa./on behalf of the company
ppa. Dr. Beate Bonefeld



Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions

ppa./on behalf of the company



Dr. Stefan Scheib
Director Global Regulatory Affairs
Centralised and Point of Care Solutions

Kontaktadresse/Contact address: Roche Diagnostics GmbH
Abt./Dept. Global Regulatory Affairs
Sandhofer Strasse 116
D-68305 Mannheim

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Hersteller/Manufacturer: Roche Diagnostics GmbH

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D-68305 Mannheim

Die Roche Diagnostics GmbH erklärt, dass das Produkt/die Produktfamilie
Roche Diagnostics GmbH declares that the product/the product line

Produktname/Product name: **Elecsys Vitamin D total**

Art.-Nr./Cat. No.: **05894913190**

Beschreibung/Description: Dieser Test dient der quantitativen Bestimmung des Gesamtgehalts an 25-Hydroxyvitamin D in Humanserum und -plasma. Dieser Test soll unterstützend für die Beurteilung von Vitamin D-Suffizienz herangezogen werden.

Elektrochemilumineszenz-Bindungstest zur Verwendung auf Elecsys und **cobas e** Immunoassay-Systemen.

This assay is intended for the quantitative determination of total 25-hydroxyvitamin D in human serum and plasma. This assay is to be used as an aid in the assessment of vitamin D sufficiency.

The electrochemiluminescence binding assay is intended for use on Elecsys and **cobas e** immunoassay analyzers.

auf das/die sich diese Erklärung bezieht, den Forderungen der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998 über In-vitro-Diagnostica (bzw. seine Umsetzung in nationales Recht der Mitgliedsstaaten in welchen das Produkt vermarktet werden soll) entspricht.

to which this declaration relates fulfils the requirements of Directive 98/79/EC of the European Parliament and Council of 27 October 1998 on in-vitro diagnostic medical devices (and its relevant transposition into the national laws of the Member States in which the device is intended to be placed on the market).

Mannheim, 18 October 2018

Roche Diagnostics GmbH

ppa./on behalf of the company

A handwritten signature in blue ink, appearing to read "R. Zielenski", written over a horizontal line.

Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions

ppa./on behalf of the company

A handwritten signature in blue ink, appearing to read "S. Scheib", written over a horizontal line.

Dr. Stefan Scheib
Director Global Regulatory Affairs
Centralised and Point of Care Solutions

Kontaktadresse/*Contact address*: Roche Diagnostics GmbH
Abt./*Dept.* Global Regulatory Affairs
Sandhofer Strasse 116
D-68305 Mannheim

EC 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: TBD (application filed; confirmation pending)

Authorized Representative: N/A
Address:

Single Registration Number: N/A

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
Elecsys Cyclosporine	07251246190	761333600440A5
Cyclosporine CalSet	05889022190	761333600371AB

Risk Class: ☐ A ☐ B ☒ C ☐ D

Conformity Route: ☐ Self-Declaration of Conformity (Class A)
☒ 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:

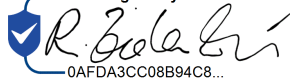
Notified Body (NB) Name: TÜV Süd Product Service GmbH
NB Address: Ridlerstraße 65
 80339 Munich
 Germany
NB Ident. No.: 0123

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

Mannheim, 17 February 2021

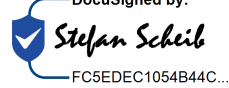
Roche Diagnostics GmbH

ppa./on behalf of the company

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Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions

ppa./on behalf of the company

DocuSigned by:

FC5EDEC1054B44C...

Dr. Stefan Scheib
Director Global Regulatory Affairs
Centralised and Point of Care Solutions

Contact address:

Roche Diagnostics GmbH
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Sandhofer Strasse 116
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