

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
ISE Cleaning Solution / Elecsys SysClean	11298500316	761333601595BA

Intended Use:

For the cleaning of ISE units on Roche/Hitachi analyzers.
 For the cleaning of Elecsys and 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.:
☐ EU Technical Documentation Assessment Certificate No. (Class D, Near-Patient Testing, Self-Testing and Companion Diagnostics):

Other: ☐ Common Specifications:

Notified Body (NB) Name: N/A
NB Address:

NB Ident. No.: N/A

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

Mannheim, 11 July 2023

Roche Diagnostics GmbH

i.V./on behalf of the company

DocuSigned by:
Christina Schmid
E3965E80F3E840E...

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

ppa./on behalf of the company

DocuSigned by:
Stefan Scheib
FC5EDEC1054B44C...

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

Contact address:

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

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Product Name	Cat. No.	Basic UDI-DI
Elecsys SysWash	11930346122	761333601654AZ

Intended Use:

Additive to the system water container for the cobas e 411 immunoassay analyzer.

The use of SysWash is mandatory for all Elecsys assays measured on cobas e 411 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.:
☐ EU Technical Documentation Assessment Certificate No. (Class D, Near-Patient Testing, Self-Testing and Companion Diagnostics):

Other: ☐ Common Specifications:

Notified Body (NB) Name: N/A
NB Address:

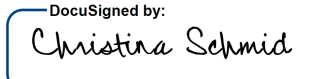
NB Ident. No.: N/A

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

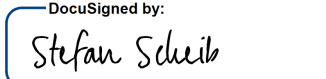
Mannheim, 19 June 2023

Roche Diagnostics GmbH

i.V./on behalf of the company

DocuSigned by:

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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 T3	09007725190	7613336010319P
Elecsys T3	09007733190	7613336010329R
Elecsys T3	09007733214	761333602588BL

Intended Use:

Immunoassay for the in vitro quantitative determination of total triiodothyronine 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
T3 CalSet	11731548122	761333601045A2

Intended Use:

T3 CalSet is used for calibrating the quantitative Elecsys T3 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:

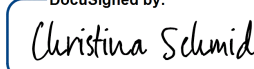
Notified Body (NB) Name: TÜV Süd Product Service GmbH
NB Address: Ridlerstraße 65
80339 Munich
Germany
NB Ident. No.: 0123

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

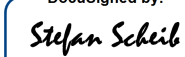
Mannheim, 14 November 2022

Roche Diagnostics GmbH

i.V./on behalf of the company

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59311CC1CDA8480...
Dr. Christina Schmid
Head of Pre-Market Quality Core Lab

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

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

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 T4**

Art.-Nr./Cat. No.: **09007741190**
09007784190

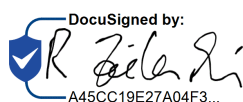
Beschreibung/Description: Immunologischer In-vitro-Test zur quantitativen Bestimmung des Thyroxin in Humanserum und -plasma.
Der ElektroChemilumineszenz ImmunoAssay "ECLIA" ist zur Durchführung an **cobas e** Immunoassay-Systemen vorgesehen.
Immunoassay for the in vitro quantitative determination of thyroxine in human serum and plasma.
*The **electrochemiluminescence immunoassay** "ECLIA" is intended for use on **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, 21 July 2020

Roche Diagnostics GmbH

ppa./on behalf of the company

DocuSigned by:

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Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions

ppa./on behalf of the company

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

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Abt./Dept. Global Regulatory Affairs
Sandhofer Strasse 116
D-68305 Mannheim

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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 Testosterone II	05200067190	761333600747B2

Intended Use:

Immunoassay for the in vitro quantitative determination of testosterone in human serum and plasma.
The electrochemiluminescence immunoassay “ECLIA” is intended for use on Elecsys and cobas e immunoassay analyzers.

Product Name	Cat. No.	Basic UDI-DI
Elecsys Testosterone II	07027915190	761333600619AQ

Intended Use:

Immunoassay for the in vitro quantitative determination of testosterone in human serum and plasma.
The electrochemiluminescence immunoassay “ECLIA” is intended for use on the cobas e 801 immunoassay analyzer.

Product Name	Cat. No.	Basic UDI-DI
Testosterone II CalSet II	05202230190	761333600748B4

Intended Use:

Testosterone II CalSet II is used for calibrating the quantitative Elecsys Testosterone 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
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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.:

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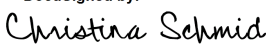
to which this declaration relates fulfils the requirements of Regulation EU 2017/746 on in-vitro diagnostic medical devices.

Mannheim, 20 March 2023

Roche Diagnostics GmbH

i.V./on behalf of the company

ppa./on behalf of the company

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Global Head of Regulatory Affairs, Core Lab

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Product Name	Cat. No.	Basic UDI-DI
Elecsys TSH	08443432190	7613336001139K
Elecsys TSH	08443432214	761333602065AF
Elecsys TSH	08429324190	7613336001129H

Intended Use:

Immunoassay for the in vitro quantitative determination of thyrotropin 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
TSH CalSet	08443459190	7613336001149M

Intended Use:

TSH CalSet is used for calibrating the quantitative Elecsys TSH 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
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Other: ☐ Common Specifications:

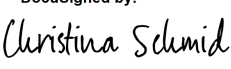
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to which this declaration relates fulfils the requirements of Regulation EU 2017/746 on in-vitro diagnostic medical devices.

Mannheim, 7 December 2022

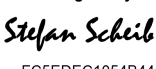
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