

## **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

<b>Product Name</b>	<b>Cat. No.</b>	<b>Basic UDI-DI</b>
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*

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

*Contact address:*

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Abt./Dept. Global Regulatory Affairs  
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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

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 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*

*ppa./on behalf of the company*

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Dr. Christina Schmid  
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Global Head of Regulatory Affairs, Core Lab

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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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Head of Pre-Market Quality Core Lab

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## 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.*

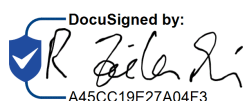
auf das/die sich diese Erklärung bezieht, den Forderungen der Richtlinie 98/79/EG des Europäischen Parlaments und  
des Rates vom 27. Oktober 1998 über In-vitro-Diagnostica (bzw. seine Umsetzung in nationales Recht der  
Mitgliedsstaaten in welchen das Produkt vermarktet werden soll) entspricht.

*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

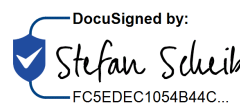
Roche Diagnostics GmbH

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Centralised and Point of Care Solutions

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

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<b>Product Name</b>	<b>Cat. No.</b>	<b>Basic UDI-DI</b>
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.

<b>Product Name</b>	<b>Cat. No.</b>	<b>Basic UDI-DI</b>
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.

<b>Product Name</b>	<b>Cat. No.</b>	<b>Basic UDI-DI</b>
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*
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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.:* 0123

*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

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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
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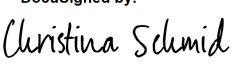
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Mannheim, 7 December 2022

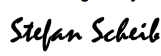
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