

## 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 Estradiol III**

Art.-Nr./Cat. No.: **07027249190**

Beschreibung/Description: Immunologischer In-vitro-Test zur quantitativen Bestimmung von Estradiol 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 estradiol in human serum and plasma.*

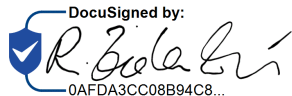
*The electrochemiluminescence immunoassay "ECLIA" is intended for use on **cobas e** immunoassay analyzers.*

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, 29 January 2021


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

DocuSigned by:  
  
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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

## **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>
Elecsys free PSA	08828601190	761333600808AV
Elecsys free PSA	08828610190	761333600809AX
Elecsys free PSA	08828610214	761333602069AP

### ***Intended Use:***

Immunoassay for the in vitro quantitative determination of free prostate-specific antigen in human serum and plasma. This assay is indicated for measurement of fPSA in conjunction with the Elecsys total PSA assay to develop a ratio (% fPSA) of fPSA to tPSA. This ratio is useful when used in conjunction with the Elecsys total PSA test as an aid in distinguishing prostate cancer from benign prostatic conditions in men age 50 years or older who have a digital rectal examination (DRE) that is not suspicious for prostate cancer and an Elecsys total PSA value in the range 4 ng/mL to 10 ng/mL. Prostate biopsy is required for the diagnosis of prostate cancer.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on cobas e immunoassay analyzers.

<b>Product Name</b>	<b>Cat. No.</b>	<b>Basic UDI-DI</b>
free PSA CalSet	08851964190	761333600811AJ

### ***Intended Use:***

free PSA CalSet is used for calibrating the quantitative Elecsys free PSA 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, 12 January 2023

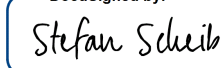
Roche Diagnostics GmbH

*i.V./on behalf of the company*

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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

*Contact address:* Roche Diagnostics GmbH  
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**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>
Elecsys FSH	08932352190	761333601701AH
Elecsys FSH	08932387190	761333601702AK
Elecsys FSH	08932387214	761333602674BE

### ***Intended Use:***

Immunoassay for the in vitro quantitative determination of follicle-stimulating hormone in human serum and plasma.

The electrochemiluminescence immunoassay “ECLIA” is intended for use on cobas e immunoassay analyzers.

<b>Product Name</b>	<b>Cat. No.</b>	<b>Basic UDI-DI</b>
FSH CalSet II	08932417190	761333601703AM
FSH CalSet II	09557440190	761333602415AL

### ***Intended Use:***

FSH CalSet II is used for calibrating the quantitative Elecsys FSH 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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- Technical Documentation Assessment Class B/C/D for Self-Testing – Annex IX
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- 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:*

*TÜV Süd Product Service GmbH  
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, 19 July 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

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*Stefan Scheib*  
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Elecsys FSH	08932387190	761333601702AK
Elecsys FSH	08932387214	761333602674BE

### ***Intended Use:***

Immunoassay for the in vitro quantitative determination of follicle-stimulating hormone in human serum and plasma.

The electrochemiluminescence immunoassay “ECLIA” is intended for use on cobas e immunoassay analyzers.

<b>Product Name</b>	<b>Cat. No.</b>	<b>Basic UDI-DI</b>
FSH CalSet II	08932417190	761333601703AM
FSH CalSet II	09557440190	761333602415AL

### ***Intended Use:***

FSH CalSet II is used for calibrating the quantitative Elecsys FSH assay on cobas e immunoassay analyzers.

**Risk Class:**  A  B  C  D

**Conformity Route:**

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<b>Product Name</b>	<b>Cat. No.</b>	<b>Basic UDI-DI</b>
Elecsys FT3 III	09005803190	7613336011329W
Elecsys FT3 III	09005811190	7613336011339Y
Elecsys FT3 III	09005811214	761333602752B9

***Intended Use:***

Immunoassay for the in vitro quantitative determination of free triiodothyronine in human serum and plasma. The electrochemiluminescence immunoassay "ECLIA" is intended for use on cobas e immunoassay analyzers.

<b>Product Name</b>	<b>Cat. No.</b>	<b>Basic UDI-DI</b>
FT3 III CalSet	09077871190	761333601134A2

***Intended Use:***

FT3 III CalSet is used for calibrating the quantitative Elecsys FT3 III 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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*Other:*  *Common Specifications:*

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*NB Address:* Ridlerstraße 65  
80339 Munich  
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*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*

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

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Global Head of Regulatory Affairs, Core Lab

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*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>
Elecsys FT4 IV	09043276190	761333600839B8
Elecsys FT4 IV	09043284190	761333600909B4
Elecsys FT4 IV	09650547190	761333602872BL

### ***Intended Use:***

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

<b>Product Name</b>	<b>Cat. No.</b>	<b>Basic UDI-DI</b>
CalSet FT4 IV	09043292190	761333600910AM

### ***Intended Use:***

CalSet FT4 IV is used for calibrating the quantitative Elecsys FT4 IV 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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- Technical Documentation Assessment Class B/C/D for Near-Patient Testing – Annex IX
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NB Ident. No.: 0123

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

Mannheim, 29 September 2023


Roche Diagnostics GmbH

i.V./on behalf of the company

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Head of Pre-Market Quality Point of Care

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

Contact address: Roche Diagnostics GmbH  
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<b>Product Name</b>	<b>Cat. No.</b>	<b>Basic UDI-DI</b>
Elecsys LH	07027575190	761333600616AJ
Elecsys LH	07027575214	761333602059AL

***Intended Use:***

Immunoassay for the in vitro quantitative determination of luteinizing hormone in human serum and plasma. The electrochemiluminescence immunoassay "ECLIA" is intended for use on cobas e immunoassay analyzers.

<b>Product Name</b>	<b>Cat. No.</b>	<b>Basic UDI-DI</b>
Elecsys LH	11732234122	761333600727AU

***Intended Use:***

Immunoassay for the in vitro quantitative determination of luteinizing hormone 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>
LH CalSet II	03561097190	761333600601A5
LH CalSet II	09557423190	761333602413AG

***Intended Use:***

LH CalSet II is used for calibrating the quantitative Elecsys LH 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:*

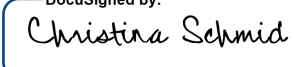
*Notified Body (NB) Name:* TÜV Süd Product Service GmbH  
*NB Address:* Ridlerstraße 65  
80339 Munich  
Germany  
*NB Ident. No.:* 0123

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

Mannheim, 15 May 2023


Roche Diagnostics GmbH

*i.V./on behalf of the company*

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Dr. Christina Schmid  
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*ppa./on behalf of the company*

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Global Head of Regulatory Affairs, Core Lab

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 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>
PreciControl Multimarker	05341787190	761333600959BK
PreciControl Multimarker	05341787922	761333600960B4

### ***Intended Use:***

PreciControl Multimarker is used for quality control of specified immunoassays 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:

***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, 12 April 2023

Roche Diagnostics GmbH

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*Christina Schmid*  
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Head of Pre-Market Quality Core Lab

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**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
PreciControl ThyroAB	05042666191	761333600667B3

### ***Intended Use:***

PreciControl ThyroAB is used for quality control of the Elecsys Anti-TSHR, Anti-TPO and Anti-Tg immunoassays 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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**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, 10 March 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

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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 IV der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998 mit TÜV SÜD Product Service GmbH (Ridlerstraße 65, 80339 München, Germany) als Notified Body (Nr. 0123)

*as per Annex IV of Directive 98/79/EC of the European Parliaments and Council of 27 October 1998 via TÜV SÜD Product Service GmbH (Ridlerstrasse 65, 80339 Munich, Germany) as the Notified Body (No. 0123)*

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: **PreciControl Tumor Marker**

Art.-Nr./Cat. No.: **11776452122**  
**11776452922 (QCS)**

Beschreibung/Description: PreciControl Tumor Marker dient zur Qualitätskontrolle von Elecsys Immunoassays auf **cobas e** Immunoassay-Analysern.

*PreciControl Tumor Marker is used for quality control of Elecsys immunoassays 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.

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Mannheim, 15 February 2022


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Head Q&R Compliance, PRRC RDG  
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