

## **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**

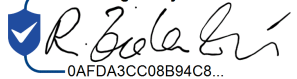
Beschreibung/Description: Immunologischer In-vitro-Test zur quantitativen Bestimmung von Estradiol in Humanserum und -plasma.  
Der ElektroChemiLumineszenz ImmunoAssay "ECLIA" ist zur Durchführung an **cobas e** Immunoassay-Systemen vorgesehen.  
*Immunoassay for the in vitro quantitative determination 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

| Product Name     | Cat. No.    | Basic UDI-DI   |
|------------------|-------------|----------------|
| 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.

| Product Name    | Cat. No.    | Basic UDI-DI   |
|-----------------|-------------|----------------|
| 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

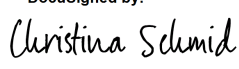
to which this declaration relates fulfils the requirements of Regulation EU 2017/746 on in-vitro diagnostic medical devices.

Mannheim, 12 January 2023

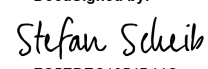
Roche Diagnostics GmbH

i.V./on behalf of the company

ppa./on behalf of the company

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

DocuSigned by:  
  
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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  
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| Product Name | Cat. No.    | Basic UDI-DI   |
|--------------|-------------|----------------|
| 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.

| Product Name  | Cat. No.    | Basic UDI-DI   |
|---------------|-------------|----------------|
| 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
- ☐ 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:*  
*NB Address:*

*TÜV Süd Product Service GmbH*  
*Ridlerstraße 65*  
*80339 Munich*  
*Germany*  
*0123*

*NB Ident. No.:*

*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

*ppa./on behalf of the company*

DocuSigned by:  
*Stefan Scheib*  
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Global Head of Regulatory Affairs, Core Lab

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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.

| Product Name  | Cat. No.    | Basic UDI-DI   |
|---------------|-------------|----------------|
| 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
- ☐ Technical Documentation Assessment Class D – Annex IX
- ☐ Technical Documentation Assessment Class B/C/D for Self-Testing – Annex IX
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*Diagnostics):*

*Other:*

☐ *Common Specifications:*

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*Ridlerstraße 65*  
*80339 Munich*  
*Germany*  
*0123*

*NB Ident. No.:*

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Mannheim, 19 July 2023

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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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Global Head of Regulatory Affairs, Core Lab

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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 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
- ☐ 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

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

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| <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
- ☐ 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:**

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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:

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Ridlerstraße 65

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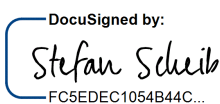
Mannheim, 29 September 2023

Roche Diagnostics GmbH

i.V./on behalf of the company

ppa./on behalf of the company

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Dr. Bernd Röttinger  
Head of Pre-Market Quality Point of Care

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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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 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.

| Product Name | Cat. No.    | Basic UDI-DI   |
|--------------|-------------|----------------|
| 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.

| Product Name | Cat. No.    | Basic UDI-DI   |
|--------------|-------------|----------------|
| 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:

NB Address:

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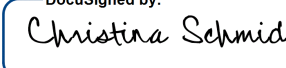
TÜV Süd Product Service GmbH  
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 80339 Munich  
 Germany  
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to which this declaration relates fulfils the requirements of Regulation EU 2017/746 on in-vitro diagnostic medical devices.

Mannheim, 15 May 2023

Roche Diagnostics GmbH

i.V./on behalf of the company

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

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Dr. Stefan Scheib  
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 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   |
|--------------------------|-------------|----------------|
| 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
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**Certificates:**

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**Other:** ☐ Common Specifications:

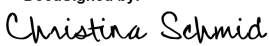
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 80339 Munich  
 Germany  
**NB Ident. No.:** 0123

*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

*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:*

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| 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)
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Mannheim, 10 March 2023

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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 Parliament 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.  
*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, 15 February 2022

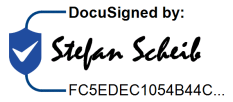
Roche Diagnostics GmbH

ppa./on behalf of the company

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Ralf Zielenski  
Head Q&R Compliance, PRRC RDG  
Centralised and Point of Care Solutions

ppa./on behalf of the company

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Dr. Stefan Scheib  
Network Lead Core Lab, Global Regulatory Affairs  
Centralised and Point of Care Solutions

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