

## **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> |
|------------------------|-------------------|---------------------|
| PreciControl Universal | 11731416190       | 7613336010439W      |
| PreciControl Universal | 11731416922 (QCS) | 7613336010449Y      |

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

PreciControl Universal is used for quality control of Elecsys 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  
☐ 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, 25 January 2023

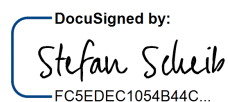
Roche Diagnostics GmbH

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

DocuSigned by:  
  
59311CC1CDA8480...

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

*ppa./on behalf of the company*

DocuSigned by:  
  
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

## **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 Parliaments and Council of 27 October 1998

Hersteller/Manufacturer: Roche Diagnostics GmbH  
Adresse/Address: Roche Professional Diagnostics  
Sandhofer Straße 116  
D-68305 Mannheim

Die Roche Diagnostics GmbH erklärt, dass das Produkt/die Produktfamilie (bei rezepturgleichen Produkten)  
*Roche Diagnostics GmbH declares that the product/the product line (in case of products manufactured by identical recipes)*

Produktname/Product name: **PreciControl Varia**

Art.-Nr./Id. No.: **05618860**

Beschreibung/Description: PreciControl Varia dient zur Qualitätskontrolle der angegebenen Elecsys Immunoassays an den Elecsys und **cobas e** Immunoassay-Systemen.  
*PreciControl Varia is used for quality control of specified Elecsys immunoassays on Elecsys and **cobas e** immunoassay analyzers.*

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

Mannheim, 09.11.2012

Roche Diagnostics GmbH

ppa./on behalf of the company

i. V./on behalf of the company



Dr. M. Thein  
Head of Quality  
Roche Professional Diagnostics



Dr. B. Rauschel  
Head of Quality Control Penzberg  
Roche Diagnostics Global Operations

Kontaktadresse/Contact address: Roche Professional Diagnostics  
Abt./Dept. Global Regulatory Affairs  
Sandhofer Straße 116  
D-68305 Mannheim  
Fax: +49 621/759 1448

05618860\_PreciControl Varia - Ia

**Roche Diagnostics GmbH**      Diagnostics Division

Roche Diagnostics GmbH; Werk Penzberg; Nonnenwald 2; D 82377 Penzberg; Telefon +49 8856 60 0; Telefax +49 8856 60 3896

Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 3962 - Geschäftsführung: Thomas Schmid, Sprecher; Edgar Vieth - Aufsichtsratsvorsitzender: Dr. Severin Schwan

## **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 Parliaments and Council of 27 October 1998

Hersteller/Manufacturer: Roche Diagnostics GmbH  
Adresse/Address: Roche Professional Diagnostics  
Sandhofer Straße 116  
D-68305 Mannheim

Die Roche Diagnostics GmbH erklärt, dass das Produkt/die Produktfamilie (bei rezepturgleichen Produkten)  
*Roche Diagnostics GmbH declares that the product/the product line (in case of products manufactured by identical recipes)*

Produktname/Product name: **PreciControl Varia**

Art.-Nr./Id. No.: **05618860**

Beschreibung/Description: PreciControl Varia dient zur Qualitätskontrolle der angegebenen Elecsys Immunoassays an den Elecsys und **cobas e** Immunoassay-Systemen.  
*PreciControl Varia is used for quality control of specified Elecsys immunoassays on Elecsys and **cobas e** immunoassay analyzers.*

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

Mannheim, 09.11.2012

Roche Diagnostics GmbH

ppa./on behalf of the company

i. V./on behalf of the company



Dr. M. Thein  
Head of Quality  
Roche Professional Diagnostics



Dr. B. Rauschel  
Head of Quality Control Penzberg  
Roche Diagnostics Global Operations

Kontaktadresse/Contact address: Roche Professional Diagnostics  
Abt./Dept. Global Regulatory Affairs  
Sandhofer Straße 116  
D-68305 Mannheim  
Fax: +49 621/759 1448

05618860\_PreciControl Varia - Ia

**Roche Diagnostics GmbH**      Diagnostics Division

Roche Diagnostics GmbH; Werk Penzberg; Nonnenwald 2; D 82377 Penzberg; Telefon +49 8856 60 0; Telefax +49 8856 60 3896

Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 3962 - Geschäftsführung: Thomas Schmid, Sprecher; Edgar Vieth - Aufsichtsratsvorsitzender: Dr. Severin Schwan

## **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 Progesterone III | 07092539190     | 761333600408A9      |
| Elecsys Progesterone III | 07027699190     | 761333600395AR      |
| Elecsys Progesterone III | 07027699214     | 761333602060A5      |

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

Immunoassay for the in vitro quantitative determination of progesterone 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> |
|-------------------------|-----------------|---------------------|
| Progesterone III CalSet | 07092547190     | 761333600409AB      |

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

Progesterone III CalSet is used for calibrating the quantitative Elecsys Progesterone 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:

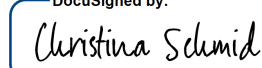
Notified Body (NB) Name: TÜV Süd Product Service GmbH  
NB Address: Ridlerstraße 65  
80339 Munich  
Germany  
NB Ident. No.: 0123

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

Mannheim, 12 January 2023

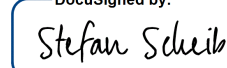
Roche Diagnostics GmbH

i.V./on behalf of the company

DocuSigned by:  
  
59311CC1CDA8480...

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

ppa./on behalf of the company

DocuSigned by:  
  
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

## **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> |
|---------------------|-----------------|---------------------|
| ProCell             | 11662988122     | 761333601645AY      |

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

System solution for generating electrochemical signals in the cobas e 411 immunoassay analyzer.  
 ProCell is used in conjunction with Elecsys assay reagents.  
 ProCell can be used with all reagent lots.

**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:**

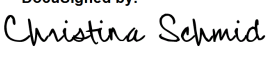
**NB Ident. No.:** N/A

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

Mannheim, 16 June 2023

Roche Diagnostics GmbH

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

DocuSigned by:  
  
E3965E80F3E840E...

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

*ppa./on behalf of the company*

DocuSigned by:  
  
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

## **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 Progesterone III | 07092539190     | 761333600408A9      |
| Elecsys Progesterone III | 07027699190     | 761333600395AR      |
| Elecsys Progesterone III | 07027699214     | 761333602060A5      |

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

Immunoassay for the in vitro quantitative determination of progesterone 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> |
|-------------------------|-----------------|---------------------|
| Progesterone III CalSet | 07092547190     | 761333600409AB      |

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

Progesterone III CalSet is used for calibrating the quantitative Elecsys Progesterone 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:

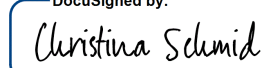
Notified Body (NB) Name: TÜV Süd Product Service GmbH  
NB Address: Ridlerstraße 65  
80339 Munich  
Germany  
NB Ident. No.: 0123

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

Mannheim, 12 January 2023

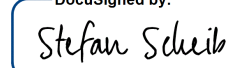
Roche Diagnostics GmbH

i.V./on behalf of the company

DocuSigned by:  
  
59311CC1CDA8480...

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

ppa./on behalf of the company

DocuSigned by:  
  
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

## **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 Prolactin II | 03203093190 | 761333600587B4 |
| Elecsys Prolactin II | 03203093214 | 761333600588B6 |

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

Immunoassay for the in vitro quantitative determination of prolactin 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 Prolactin II | 07027737190 | 761333600617AL |
| Elecsys Prolactin II | 07027737214 | 761333602061A7 |

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

Immunoassay for the in vitro quantitative determination of prolactin 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   |
|---------------------|-------------|----------------|
| Prolactin II CalSet | 03277356190 | 761333600591AT |

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

Prolactin II CalSet is used for calibrating the quantitative Elecsys Prolactin 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
- ☐ 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

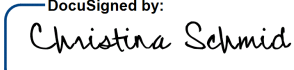
NB Ident. No.:

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

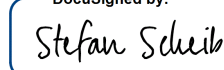
Mannheim, 31 March 2023

Roche Diagnostics GmbH

i.V./on behalf of the company

DocuSigned by:  
  
E3965E80F3E840E...  
Dr. Christina Schmid  
Head of Pre-Market Quality Core Lab

ppa./on behalf of the company

DocuSigned by:  
  
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

## **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 total PSA   | 08791686190     | 761333600805AP      |
| Elecsys total PSA   | 08791732190     | 761333600807AT      |
| Elecsys total PSA   | 08791732214     | 761333602067AK      |
| Elecsys total PSA   | 09744860190     | 761333602871BJ      |

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

This assay, a quantitative in vitro diagnostic test for total (free + complexed) prostate-specific antigen (tPSA) in human serum and plasma, is indicated for the measurement of total PSA in conjunction with digital rectal examination (DRE) as an aid in the detection of prostate cancer in men aged 50 years or older. Prostate biopsy is required for diagnosis of prostate cancer. The test is further indicated for serial measurement of tPSA to aid in the management of cancer patients.

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 total PSA   | 08791716190     | 761333600806AR      |

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

This assay, a quantitative in vitro diagnostic test for total (free + complexed) prostate-specific antigen (tPSA) in human serum and plasma, is indicated for the measurement of total PSA in conjunction with digital rectal examination (DRE) as an aid in the detection of prostate cancer in men aged 50 years or older. Prostate biopsy is required for diagnosis of prostate cancer. The test is further indicated for serial measurement of tPSA to aid in the management of cancer patients.

The electrochemiluminescence immunoassay "ECLIA" is intended for use on cobas e 601 and cobas e 602 immunoassay analyzers.

| <b>Product Name</b> | <b>Cat. No.</b> | <b>Basic UDI-DI</b> |
|---------------------|-----------------|---------------------|
| total PSA CalSet    | 08838534190     | 761333600810AG      |

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

total PSA CalSet II is used for calibrating the quantitative Elecsys total 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:*

*NB Address:*

*NB Ident. No.:*

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

DocuSigned by:  
  
00ABEBB0E89341C...

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

*ppa./on behalf of the company*

DocuSigned by:  
  
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

## **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 PTH         | 11972103122     | 761333601655B3      |
| Elecsys PTH STAT    | 04892470190     | 761333601498BB      |

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

Immunoassay for the in vitro quantitative determination of intact parathyroid hormone in human serum and plasma for the differential diagnosis of hypercalcemia and hypocalcemia. This assay can be used intraoperatively. 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 PTH         | 07251068190     | 761333601500A5      |

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

Immunoassay for the in vitro quantitative determination of intact parathyroid hormone in human serum and plasma for the differential diagnosis of hypercalcemia and hypocalcemia. This assay can be used intraoperatively. 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 PTH          | 08243875190     | 761333601541AK      |

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

CalSet PTH is used for calibrating the quantitative Elecsys PTH assay for intact PTH (parathyroid hormone) on the Elecsys and cobas e immunoassay analyzers.

| <b>Product Name</b> | <b>Cat. No.</b> | <b>Basic UDI-DI</b> |
|---------------------|-----------------|---------------------|
| CalSet PTH STAT     | 08243930190     | 761333601543AP      |

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

CalSet PTH STAT is used for calibrating the quantitative Elecsys PTH STAT assay for intact PTH (parathyroid hormone) on the Elecsys and cobas e immunoassay analyzers.

| Product Name  | Cat. No.    | Basic UDI-DI   |
|---------------|-------------|----------------|
| CalSet II PTH | 08243891190 | 761333601542AM |

**Intended Use:**

CalSet II PTH is used for calibrating the quantitative Elecsys PTH assay for intact PTH (parathyroid hormone) 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:

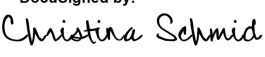
**Notified Body (NB) Name:** TÜV Süd Product Service GmbH  
**NB Address:** Ridlerstraße 65  
 80339 Munich  
 Germany  
**NB Ident. No.:** 0123

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

Mannheim, 31 March 2023

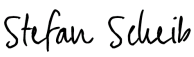
Roche Diagnostics GmbH

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

DocuSigned by:  
  
E3965E80F3E840E...

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

*ppa./on behalf of the company*

DocuSigned by:  
  
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