DocuSign Envelope ID: 4042BA88-BFB0-475C-8782-91743C29B095

EU Declaration of Conformity

as per Annex IV of the Regulation EU 2017/746 on in-vitro diagnostic medical devices

Manufacturer:
Address:

Roche Diagnostics GmbH
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 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*

Digitally signed by Lazari Cristina
Date: 2024.12.04 16:51:12 EET
Reason: MoldSign Signature
Location: Moldova

Roche Diagnostics GmbH; Sandhofer Straße 116; D-68305 Mannheim; Telefon +49-621-759-0; Telefax +49-621-759-2890

Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 3962 - Geschäftsführung: Dr. Claudia Fleischer; Clemens Schmid - Aufsichtsratsvorsitzender: Dr. Thomas Schinecker

DocuSign Envelope ID: 4042BA88-BFB0-475C-8782-91743C29B095

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:
Christina Schmid
59311CC1CDA8480...

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

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*

Dr. M. Thein
Head of Quality
Roche Professional Diagnostics

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

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

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*

Dr. M. Thein
Head of Quality
Roche Professional Diagnostics

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

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

Kontaktadresse/*Contact address*: Roche Professional Diagnostics
Abt./*Dept.* Global Regulatory Affairs
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Fax: +49 621/759 1448

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

DocuSign Envelope ID: 11315BCF-BC03-43AC-9C41-CB3FEE058A87

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 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.

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

Roche Diagnostics GmbH; Sandhofer Straße 116; D-68305 Mannheim; Telefon +49-621-759-0; Telefax +49-621-759-2890

Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 3962 - Geschäftsführung: Dr. Claudia Fleischer; Clemens Schmid - Aufsichtsratsvorsitzender: Dr. Thomas Schinecker

DocuSign Envelope ID: 11315BCF-BC03-43AC-9C41-CB3FEE058A87

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:
Christina Schmid
59311CC1CDA8480...

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

ppa./*on behalf of the company*

DocuSigned by:
Stefan Scheib
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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

DocuSign Envelope ID: AFC21951-A0A7-4093-B184-76AA17249005

EU Declaration of Conformity

as per Annex IV of the Regulation EU 2017/746 on in-vitro diagnostic medical devices

Manufacturer:
Address:

Roche Diagnostics GmbH
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**
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.

Roche Diagnostics GmbH; Sandhofer Straße 116; D-68305 Mannheim; Telefon +49-621-759-0; Telefax +49-621-759-2890

Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 3962 - Geschäftsführung: Dr. Claudia Fleischer; Clemens Schmid - Aufsichtsratsvorsitzender: Dr. Thomas Schinecker

DocuSign Envelope ID: AFC21951-A0A7-4093-B184-76AA17249005

Mannheim, 16 June 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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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

DocuSign Envelope ID: 11315BCF-BC03-43AC-9C41-CB3FEE058A87

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 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.

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

Roche Diagnostics GmbH; Sandhofer Straße 116; D-68305 Mannheim; Telefon +49-621-759-0; Telefax +49-621-759-2890

Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 3962 - Geschäftsführung: Dr. Claudia Fleischer; Clemens Schmid - Aufsichtsratsvorsitzender: Dr. Thomas Schinecker

DocuSign Envelope ID: 11315BCF-BC03-43AC-9C41-CB3FEE058A87

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:
Christina Schmid
59311CC1CDA8480...

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

DocuSign Envelope ID: 01EF01C3-C66C-4B77-B93C-ABABD9615E94

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*

Roche Diagnostics GmbH; Sandhofer Straße 116; D-68305 Mannheim; Telefon +49-621-759-0; Telefax +49-621-759-2890

Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 3962 - Geschäftsführung: Dr. Claudia Fleischer; Clemens Schmid - Aufsichtsratsvorsitzender: Dr. Thomas Schinecker

DocuSign Envelope ID: 01EF01C3-C66C-4B77-B93C-ABABD9615E94

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, 31 March 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
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

DocuSign Envelope ID: 43472E95-06AD-4829-9F83-1529957D29AE

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 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.

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

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

Roche Diagnostics GmbH; Sandhofer Strasse 116; D-68305 Mannheim; Telefon +49-621-759-0; Telefax +49-621-759-2890
Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 3962 - Geschäftsführung: Claus Haberda; Clemens Schmid - Aufsichtsratsvorsitzender: Dr. Thomas Schinecker

DocuSign Envelope ID: 43472E95-06AD-4829-9F83-1529957D29AE

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:
Bernd Röttinger
00ABEBB0E89341C...

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

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

DocuSign Envelope ID: 01EF01C3-C66C-4B77-B93C-ABABD9615E94

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 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.

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

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

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

Roche Diagnostics GmbH; Sandhofer Straße 116; D-68305 Mannheim; Telefon +49-621-759-0; Telefax +49-621-759-2890

Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 3962 - Geschäftsführung: Dr. Claudia Fleischer; Clemens Schmid - Aufsichtsratsvorsitzender: Dr. Thomas Schinecker

DocuSign Envelope ID: 01EF01C3-C66C-4B77-B93C-ABABD9615E94

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*

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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:
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E3965E80F3E840E...

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