

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 Anti-Tg	09004998190	7613336011419X
Elecsys Anti-Tg	09005021190	7613336011429Z
Elecsys Anti-Tg	09005021214	761333602092AJ

Intended Use:

Immunoassay for the in vitro quantitative determination of antibodies to thyroglobulin in human serum and plasma. The anti-Tg determination is used as an aid in the detection of autoimmune thyroid diseases. The electrochemiluminescence immunoassay "ECLIA" is intended for use on cobas e immunoassay analyzers.

Product Name	Cat. No.	Basic UDI-DI
Anti-Tg CalSet	09005030190	761333601143A3

Intended Use:

Anti-Tg CalSet is used for calibrating the quantitative Elecsys Anti-Tg 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

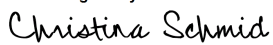
to which this declaration relates fulfils the requirements of Regulation EU 2017/746 on in-vitro diagnostic medical devices.

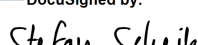
Mannheim, 31 January 2024

Roche Diagnostics GmbH

i.V./on behalf of the company

ppa./on behalf of the company

DocuSigned by:

E3965E80F3E840E...

DocuSigned by:

FC5EDEC1054B44C...

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

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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Product Name	Cat. No.	Basic UDI-DI
Elecsys CA 15-3 II	07027001190	761333600791B5
Elecsys CA 15-3 II	07027001214	761333602049AH
Elecsys CA 15-3 II	09755594190	761333602861BF

Intended Use:

Immunological in vitro assay for quantitative determination of CA 15-3 in human serum and plasma to aid in the management of breast cancer patients. In conjunction with other clinical and diagnostic procedures, serial testing with this assay is an aid

- in the early detection of recurrence in previously treated stage II and III breast cancer patients
- for monitoring response to therapy in metastatic breast cancer patients

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

Product Name	Cat. No.	Basic UDI-DI
Elecsys CA 15-3 II	03045838122	761333600576AX
Elecsys CA 15-3 II	03045838214	761333602587BJ

Intended Use:

Immunological in vitro assay for quantitative determination of CA 15-3 in human serum and plasma to aid in the management of breast cancer patients. In conjunction with other clinical and diagnostic procedures, serial testing with this assay is an aid

- in the early detection of recurrence in previously treated stage II and III breast cancer patients
- for monitoring response to therapy in metastatic breast cancer patients

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

Product Name	Cat. No.	Basic UDI-DI
CA 15-3 II CalSet	03045846122	761333600577AZ

Intended Use:

CA 15-3 II CalSet is used for calibrating the quantitative Elecsys CA 15-3 II assay on cobas e immunoassay analyzers.

Risk Class: ☐ A ☐ B ☒ C ☐ D

Conformity Route:

- ☐ Self-Declaration of Conformity (Class A)
- ☐ Self-Declaration of Conformity after Notified Body involvement for sterile manufacturing conditions acc. Art. 48 (10) (Class A sterile)
- ☒ Technical Documentation Assessment Class B/C – Annex IX
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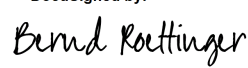
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Mannheim, 29 September 2023

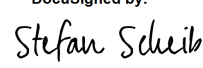
Roche Diagnostics GmbH

i.V./on behalf of the company

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

ppa./on behalf of the company

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

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Product Name	Cat. No.	Basic UDI-DI
Elecsys DHEA-S	03000087122	761333600572AP
Elecsys DHEA-S	07027192190	761333600801AF

Intended Use:

Immunoassay for the in vitro quantitative determination of dehydroepiandrosterone sulfate (DHEA-S) 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
DHEA-S CalSet	03000095122	761333600573AR

Intended Use:

Intended use DHEA-S CalSet is used for calibrating the quantitative Elecsys DHEA-S 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:

- ☒ 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.:

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

Mannheim, 12 April 2024

Roche Diagnostics GmbH

i.V./on behalf of the company

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

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Dr. Stefan Scheib
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Product Name	Cat. No.	Basic UDI-DI
Elecsys Estradiol III	06656021190	761333600218A2
Elecsys Estradiol III	06656021214	761333602047AD

Intended Use:

Immunoassay for the in vitro quantitative determination of estradiol 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 Estradiol III	07027249190	761333600252A2
Elecsys Estradiol III	07027249214	761333602054AA

Intended Use:

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.

Product Name	Cat. No.	Basic UDI-DI
Estradiol III CalSet	06656048190	761333600219A4

Intended Use:

Estradiol III CalSet is used for calibrating the quantitative Elecsys Estradiol 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
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Other:

- ☐ Common Specifications:

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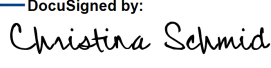
TÜV Süd Product Service GmbH
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80339 Munich
Germany
0123

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

Mannheim, 30 March 2023

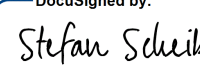
Roche Diagnostics GmbH

i.V./on behalf of the company

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

ppa./on behalf of the company

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Dr. Stefan Scheib
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

Product Name	Cat. No.	Basic UDI-DI
Elecsys Folate III	08324131190	761333601151A2

Intended Use:

Binding assay for the in vitro quantitative determination of folate in human serum and plasma. Folate measurements, performed with the Elecsys Folate III assay, are used as an aid in diagnosis and monitoring of folate imbalance. The electrochemiluminescence immunoassay "ECLIA" is intended for use on cobas e immunoassay analyzers.

Product Name	Cat. No.	Basic UDI-DI
Elecsys Folate III	08324174190	761333601153A6

Intended Use:

Binding assay for the in vitro quantitative determination of folate in human serum, plasma and erythrocytes (red blood cells, RBC). Folate measurements, performed with the Elecsys Folate III assay, are used as an aid in diagnosis and monitoring of folate imbalance.

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

Product Name	Cat. No.	Basic UDI-DI
Folate III CalSet	08324182190	761333601152A4

Intended Use:

Folate III CalSet is used for calibrating the quantitative Elecsys Folate III assay on cobas e immunoassay analyzers.

Product Name	Cat. No.	Basic UDI-DI
CalSet Folate	08324247190	761333601154A8

Intended Use:

CalSet Folate is used for calibrating the quantitative Elecsys Folate 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
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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:

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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
Abt./Dept. Global Regulatory Affairs
Sandhofer Strasse 116
D-68305 Mannheim

EU Declaration of Conformity

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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
Elecsys free PSA	09744908190	761333602994C3

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

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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, 1 August 2024

Roche Diagnostics GmbH

i.V./on behalf of the company

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Site Quality Head / Network Lead Penzberg

ppa./on behalf of the company

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

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Sandhofer Strasse 116
D-68305 Mannheim

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Roche Diagnostics GmbH declares, under the sole responsibility, that the product/the product line

Product Name	Cat. No.	Basic UDI-DI
Elecsys FSH	07027346190	761333600612AA

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 the cobas e 801 immunoassay analyzer.

Product Name	Cat. No.	Basic UDI-DI
Elecsys FSH	11775863122	761333600729AY

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 Elecsys and cobas e immunoassay analyzers.

Product Name	Cat. No.	Basic UDI-DI
FSH CalSet II	03032680122	761333600574AT

Intended Use:

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

Risk Class: ☐ A ☒ B ☐ C ☐ D

Conformity Route:

- ☐ Self-Declaration of Conformity (Class A)
- ☐ Self-Declaration of Conformity after Notified Body involvement for sterile manufacturing conditions acc. Art. 48 (10) (Class A sterile)
- ☒ Technical Documentation Assessment Class B/C – Annex IX
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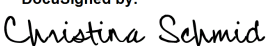
Notified Body (NB) Name: TÜV Süd Product Service GmbH
NB Address: Ridlerstraße 65
80339 Munich
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Mannheim, 15 March 2023

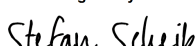
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Global Head of Regulatory Affairs, Core Lab

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Product Name	Cat. No.	Basic UDI-DI
Elecsys LH	11732234122	761333600727AU
Elecsys LH	07027575190	761333600616AJ
Elecsys LH	07027575214	761333602059AL
Elecsys LH	09755721190	761333602985C2

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
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)
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Other:

☐ Common Specifications:

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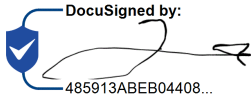
NB Ident. No.: 0123

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

Mannheim, 12 August 2024

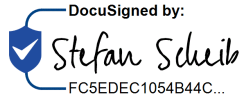
Roche Diagnostics GmbH

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Dr. Peer Lorenz
Site Quality Head / Network Lead, Mannheim

ppa./on behalf of the company

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

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Product Name	Cat. No.	Basic UDI-DI
Elecsys N-MID Osteocalcin	12149133122	7613336010539Z

Intended Use:

Immunoassay for the in vitro quantitative determination of N-MID osteocalcin in human serum and plasma. The determination is used for the control of antiresorptives therapeutic efficiency, e.g. for patients with osteoporosis or hypercalcemia.

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

Product Name	Cat. No.	Basic UDI-DI
Elecsys N-MID Osteocalcin	07027591190	761333600995BP

Intended Use:

Immunoassay for the in vitro quantitative determination of N-MID osteocalcin in human serum and plasma. The determination is used for the control of antiresorptives therapeutic efficiency, e.g. for patients with osteoporosis or hypercalcemia.

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

Product Name	Cat. No.	Basic UDI-DI
N-MID Osteocalcin CalSet	11972111122	761333601048A8

Intended Use:

N-MID Osteocalcin CalSet is used for calibrating the quantitative Elecsys N-MID Osteocalcin 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, 25 April 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

Product Name	Cat. No.	Basic UDI-DI
Elecsys Progesterone III	07092539190	761333600408A9
Elecsys Progesterone III	07027699190	761333600395AR
Elecsys Progesterone III	07027699214	761333602060A5
Elecsys Progesterone III	09755748190	761333602860BD

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:

Notified Body (NB) Name:
NB Address:

TÜV Süd Product Service GmbH
Ridlerstraße 65
80339 Munich
Germany
0123

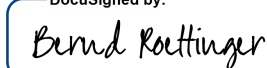
NB Ident. No.:

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

Mannheim, 29 September 2023

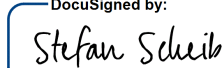
Roche Diagnostics GmbH

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:

FC5EDEEC1054B44C...

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 Tg II	08906556190	7613336010249S
Elecsys Tg II	08906564190	7613336010259U
Elecsys Tg II	08906564214	761333602072AC

Intended Use:

Immunoassay for the in vitro quantitative determination of thyroglobulin in human serum and plasma.
 Determination of Tg is used as an aid in monitoring after thyroid ablation.
 The electrochemiluminescence immunoassay "ECLIA" is intended for use on cobas e immunoassay analyzers.

Product Name	Cat. No.	Basic UDI-DI
Tg II CalSet	08991405190	761333601028A2

Intended Use:

Tg II CalSet is a lyophilized equine serum with added thyroglobulin in 2 concentration ranges.
 The CalSet 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.: 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, 6 October 2023

Roche Diagnostics GmbH

i.V./on behalf of the company

DocuSigned by:

00ABEBB0E89341C...

Dr. Bernd Röttinger
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