

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 CEA	11731629322	7613336001349T

Intended Use:

Immunoassay for the in vitro quantitative determination of carcinoembryonic antigen in human serum and plasma. This assay is further indicated for serial measurement of CEA to aid in the management of cancer patients. The electrochemiluminescence immunoassay "ECLIA" is intended for use on Elecsys and cobas e immunoassay analyzers.

Product Name	Cat. No.	Basic UDI-DI
Elecsys CEA	04491777190	761333600279AN
Elecsys CEA	07027079190	761333600248AB
Elecsys CEA	07027079214	761333602051A4
Elecsys CEA	09755616190	761333602866BR

Intended Use:

Immunoassay for the in vitro quantitative determination of carcinoembryonic antigen in human serum and plasma. This assay is further indicated for serial measurement of CEA 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
CEA CalSet	11731645322	7613336001359V

Intended Use:

CEA CalSet is used for calibrating the quantitative Elecsys CEA 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, 1 August 2024

Roche Diagnostics GmbH

i.V./on behalf of the company

DocuSigned by:
 Klaus Riebel
5E57330EEFE04C4...

Dr. Klaus Riebel
Site Quality Head / Network Lead Penzberg

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

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
CleanCell M	04880293190	761333601330A4
CleanCell M	04880293214	761333602614AU

Intended Use:

System solution for cleaning the functional areas of the indicated cobas e immunoassay analyzers. CleanCell M is used in conjunction with Elecsys assay reagents. CleanCell M 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, 22 June 2023

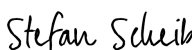
Roche Diagnostics GmbH

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

HITACHI

EU Declaration of Conformity

Manufacturer: Hitachi High-Tech Corporation
Address: 1-17-1 Toranomon, Minato-ku Tokyo 105-6409, JAPAN

Single Registration Number: JP-MF-000016991

European Representative: Roche Diagnostics GmbH
Address: Sandhofer Strasse 116, 68305 Mannheim, Germany

Product Name: **cobas® pro integrated solutions**

We, Hitachi High-Tech Corporation, declare under our sole responsibility that the above listed device(s) is/are in conformity with the following European Union harmonisation legislation:

- REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU
- DIRECTIVE (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances
- DIRECTIVE 2014/53/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC

Intended use/purpose: cobas® pro integrated solutions is an automated analyzer, intended for running qualitative, semi-quantitative and quantitative clinical chemistry and immunochemistry assays as well as ion selective measurements.

See the configurable device list on page 2 for details.

Notified Body's name/
number (if applicable): Not applicable

IVDR conformity
assessment procedures: Annex II and III of REGULATION (EU) 2017/746 (Class A)

Applied standards: See Appendix I

Starting Serial No.: See Appendix II

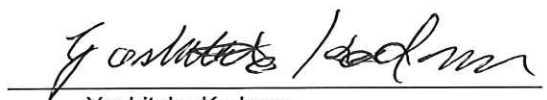
on behalf of the company

Date: 27 Jun 2022


Yoshihiro Kawabe
General Manager
Medical Systems Quality Assurance Dep't
Corporate Quality Assurance Div.
Hitachi High-Tech Corporation

on behalf of the company

Date: 27 Jun 2022


Yoshitaka Kodama
General Manager
Life & Medical Systems Center
Life & Medical Systems Business Div.
Analytical & Medical Solution Business Group
Hitachi High-Tech Corporation

Contact address:
Hitachi High-Tech Corporation

Configurable device list of cobas® pro integrated solutions

Product name or component name	Basic UDI-DI	Order information	Risk Class for REGULATION (EU) 2017/746
cobas pro SSU	761333601776BG	09205632001	Class A
cobas pro SB	761333601777BJ	09205675001	Class A
cobas pro SBL c 503	761333601779BN	09205691001	Class A
cobas pro SBL e 801	761333601781B9	09211888001	Class A
cobas pro transport line	761333601778BL	09205683001	Class A
cobas pro Transport Belt (2 AU, 2 ISE)	761333602140A4	09205713001	Class A
cobas pro Transport Belt (3 AU, 2 ISE)		09205721001	Class A
cobas pro Transport Belt (4 AU, 2 ISE)		09205730001	Class A
cobas pro B-Gate Upgrade Kit	761333601780B7	09205756001	Class A
cobas pro B-Gate update kit	761333601609AU	08763640001	Class A
cobas pro liquid waste container	761333601610AD	08763704001	Class A

Appendix I
List of applied standards:

REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU:

Standard number, year	Name of applied standard
EN ISO 13485: 2016	Medical devices – Quality management systems - Requirements for regulatory purposes
EN ISO 14971: 2012	Medical devices - Application of risk management to medical devices
EN 62304: 2006 / AC: 2008	Medical device software - Software life-cycle processes
EN 62366: 2008 / A1 2015	Medical devices - Application of usability engineering to medical devices
EN 13612: 2002	Performance evaluation of in vitro diagnostic medical devices
EN ISO 18113-1: 2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) - Part 1: Terms, definitions and general requirements
EN ISO 18113-3: 2011	In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) - Part 3: In vitro diagnostic instruments for professional use
EN ISO 15223-1:2016	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements
IEC 61010-2-101: 2015	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
IEC 61326-2-6: 2012/ EN 61326-2-6:2013	Electrical equipment for measurement, control and laboratory use – EMC requirements – Part 2-6: Particular requirements – In vitro diagnostic (IVD) medical equipment

DIRECTIVE (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances:

Standard number, year	Name of applied standard
EN IEC 63000:2018	Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances

DIRECTIVE 2014/53/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC:

Standard number, year	Name of applied standard
EN 300 330 V2.1.1	Short Range Devices (SRD); Radio equipment in the frequency range 9 kHz to 25 MHz and inductive loop systems in the frequency range 9 kHz to 30 MHz
IEC 61010-2-101: 2015	Safety requirements for electrical equipment for measurement, control, and laboratory use - Part 2-101: Particular requirements for in vitro diagnostic (IVD) medical equipment
EN 62479:2010:	Assessment of the compliance of low power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz)
EN 301 489-1 V1.9.2:	Electro Magnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements
EN 301 489-3 V1.6.1:	Electromagnetic compatibility and Radio spectrum Matters (ERM); Electro-Magnetic Compatibility (EMC) standard for radio equipment and services; Part 3: Specific conditions for Short-Range Devices (SRD) operating on frequencies between 9 kHz and 246 GHz

Appendix II
List of applicable product name and serial number

REGULATION (EU) 2017/746 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on in vitro diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU:

Product name or component name	Starting serial number
cobas pro SSU	From 2201-01 onward (Japan shipment) From C201-01 onward (China shipment)
cobas pro SB	From 2201-01 onward (Japan shipment) From C201-01 onward (China shipment)
cobas pro SBL c 503	From 2201-01 onward (Japan shipment) From C201-01 onward (China shipment)
cobas pro SBL e 801	From 2201-01 onward (Japan shipment) From C201-01 onward (China shipment)
cobas pro transport line	From 2201-01 onward (Japan shipment) From C201-01 onward (China shipment)
cobas pro Transport Belt (2 AU, 2 ISE)	Shipment from March 2022 onward
cobas pro Transport Belt (3 AU, 2 ISE)	
cobas pro Transport Belt (4 AU, 2 ISE)	
cobas pro B-Gate Upgrade Kit	
cobas pro B-Gate update kit	
cobas pro liquid waste container	

Appendix II
List of applicable product name and serial number (cont.)

DIRECTIVE (EU) 2015/863 of 31 March 2015 amending Annex II to Directive 2011/65/EU of the European Parliament and of the Council as regards the list of restricted substances:

Product name or component name	Starting serial number
cobas pro SSU	From 2001-06 onward (Japan shipment) Shipment from July 2021 onward (China shipment)
cobas pro SB	From 2001-06 onward (Japan shipment) Shipment from July 2021 onward (China shipment)
cobas pro SBL c 503	From 2001-01 onward (Japan shipment) Shipment from July 2021 onward (China shipment)
cobas pro SBL e 801	From 2001-01 onward (Japan shipment) Shipment from July 2021 onward (China shipment)
cobas pro transport line	From 2001-01 onward (Japan shipment) Shipment from July 2021 onward (China shipment)
cobas pro Transport Belt (2 AU, 2 ISE)	Shipment from March 2021 onward
cobas pro Transport Belt (3 AU, 2 ISE)	
cobas pro Transport Belt (4 AU, 2 ISE)	
cobas pro B-Gate Upgrade Kit	From 211523-01 onward
cobas pro B-Gate update kit	From 210744-01 onward
cobas pro liquid waste container	Shipment from March 2021 onward

End of the document

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 Cortisol II	06687733190	761333600794BB

Intended Use:

Immunoassay for the in vitro quantitative determination of cortisol in human serum, plasma and saliva. The determination of cortisol is used for the recognition and treatment of functional disorders of the adrenal gland. The electrochemiluminescence immunoassay "ECLIA" is intended for use on Elecsys and cobas e immunoassay analyzers.

Product Name	Cat. No.	Basic UDI-DI
Elecsys Cortisol II	07027150190	761333600800AD

Intended Use:

Immunoassay for the in vitro quantitative determination of cortisol in human serum, plasma and saliva. The determination of cortisol is used for the recognition and treatment of functional disorders of the adrenal gland. The electrochemiluminescence immunoassay "ECLIA" is intended for use on cobas e immunoassay analyzers.

Product Name	Cat. No.	Basic UDI-DI
Cortisol II CalSet	06687750190	761333600795BD

Intended Use:

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

Product Name	Cat. No.	Basic UDI-DI
PreciControl Cortisol Saliva	06687768190	761333600796BF

Intended Use:

PreciControl Cortisol Saliva is used for quality control of the Elecsys Cortisol II immunoassay 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:

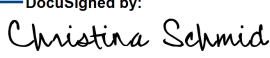
Notified Body (NB) Name: TÜV Süd Product Service GmbH
 NB Address: Ridlerstraße 65
 80339 Munich
 Germany
 NB Ident. No.: 0123

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

Mannheim, 26 April 2023

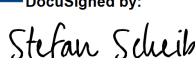
Roche Diagnostics GmbH

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

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
 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 C-Peptide	03184897190	761333600931AV
Elecsys C-Peptide	03184897214	761333602044A7

Intended Use:

Immunoassay for the in vitro quantitative determination of C-peptide in human serum, plasma and urine. The assay is intended for use as an aid in the diagnosis and treatment of patients with abnormal insulin secretion. The electrochemiluminescence immunoassay "ECLIA" is intended for use on Elecsys and cobas e immunoassay analyzers.

Product Name	Cat. No.	Basic UDI-DI
Elecsys C-Peptide	07027168190	761333600993BK
Elecsys C-Peptide	07027168214	761333602053A8

Intended Use:

Immunoassay for the in vitro quantitative determination of C-peptide in human serum, plasma and urine. The assay is intended for use as an aid in the diagnosis and treatment of patients with abnormal insulin secretion. The electrochemiluminescence immunoassay "ECLIA" is intended for use on cobas e immunoassay analyzers.

Product Name	Cat. No.	Basic UDI-DI
C-Peptide CalSet	03184919190	761333600932AX

Intended Use:

C-Peptide CalSet is used for calibrating the quantitative Elecsys C-Peptide 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.:

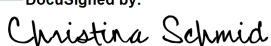
TÜV Süd Product Service GmbH
 Ridlerstraße 65
 80339 Munich
 Germany
 0123

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

Mannheim, 30 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

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

Contact address:

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

EG-Konformitätserklärung/EC Declaration of Conformity

gemäß Anhang 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: **Diluent Universal**

Art.-Nr./Cat. No.: **07299001190**

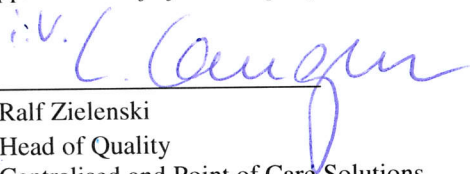
Beschreibung/Description: Diluent Universal dient als Verdünnungsmedium für Proben in
Verbindung mit Elecsys Test-Reagenzien.
*Diluent Universal is used as a sample diluent in conjunction with
Elecsys assay reagents.*

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-Diagnostika 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, 02 June 2016

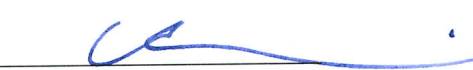
Roche Diagnostics GmbH

ppa./on behalf of the company



Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions

ppa./on behalf of the company



Dr. Peter Martin
Senior 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

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Single Registration Number: DE-MF-000006260

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Product Name	Cat. No.	Basic UDI-DI
Elecsys FT3 III	09005803190	7613336011329W
Elecsys FT3 III	09005811190	7613336011339Y
Elecsys FT3 III	09005811214	761333602752B9
Elecsys FT3 III	09745874190	761333602873BN

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.

Product Name	Cat. No.	Basic UDI-DI
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

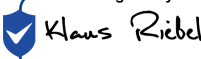
NB Ident. No.: 0123

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

Mannheim, 7 August 2024

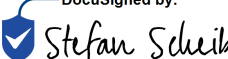
Roche Diagnostics GmbH

i.V./on behalf of the company

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Dr. Klaus Riebel
Site Quality Head / Network Lead Penzberg

ppa./on behalf of the company

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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

Product Name	Cat. No.	Basic UDI-DI
Elecsys FT4 IV	09043276190	761333600839B8
Elecsys FT4 IV	09043284190	761333600909B4
Elecsys FT4 IV	09043284214	761333602939BT
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.

Product Name	Cat. No.	Basic UDI-DI
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

☐ 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 August 2024

Roche Diagnostics GmbH

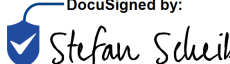
ppa./on behalf of the company

DocuSigned by:

485913ABEB04408...

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

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 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: **Elecsys HBeAg**

Art.-Nr./Cat. No.: **07027427190**

Beschreibung/Description: Immunologischer In-vitro-Test zur qualitativen Bestimmung von Hepatitis B e Antigen (HBeAg) in Humanserum und -plasma. Der ElektroChemilumineszenz ImmunoAssay "ECLIA" ist zur Durchführung an **cobas e** Immunoassay-Systemen vorgesehen.
*Immunoassay for the in vitro qualitative determination of hepatitis B e antigen (HBeAg) 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, 21 September 2021

Roche Diagnostics GmbH

ppa./on behalf of the company

DocuSigned by:

A7F0BA9FE91A46A...

Ralf Zielenski
Head Q&R Compliance, PRRC RDG
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

Amendment to IVDD EC Declaration of Conformity

pursuant to Article 110 (3) of EU 2017/746 (IVDR) concerning in vitro diagnostic medical devices

Manufacturer: Roche Diagnostics GmbH

Address: Sandhofer Strasse 116
68305 Mannheim
Germany

This amendment is only valid in combination with the following EC Declaration of Conformity (IVDD):

Product Name: Elecsys HBsAg II

Cat. No.:
08814848190

Signed on: 15-Feb-2021

*This Amendment confirms the validity of the aforementioned EC Declaration of Conformity (IVDD).
It considers clarification of scope statements, scope reductions and changes to the manufacturer data initiated 26 May 2022 or later.*

Description of change:

Addition of a new catalogue number 08814848192 for a new package size ("multi pack/maxi pack") of the product Elecsys HBsAg II.

Intended Use:

Immunologischer In-vitro-Test zur qualitativen Bestimmung von Hepatitis-B Oberflächenantigen (HBsAg) in Humanserum und -plasma.

Der ElektroChemiLumineszenz ImmunoAssay "ECLIA" ist zur Durchführung an cobas e Immunoassay-Systemen vorgesehen.

Immunoassay for the in vitro qualitative determination of hepatitis B surface antigen (HBsAg) in human serum and plasma.

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

Mannheim, 18 August 2023

Roche Diagnostics GmbH

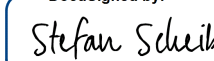
i.V./on behalf of the company

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 IgE II	04827031190	761333600657AY
Elecsys IgE II	04827031214	761333602046AB

Intended Use:

Immunoassay for the in vitro quantitative determination of immunoglobulin E in human serum and plasma.
Determination of total IgE is useful as an aid in the diagnosis of allergic diseases.
The electrochemiluminescence immunoassay “ECLIA” is intended for use on Elecsys and cobas e immunoassay analyzers.

Product Name	Cat. No.	Basic UDI-DI
Elecsys IgE II	07027516190	761333600614AE
Elecsys IgE II	07027516214	761333602057AG

Intended Use:

Immunoassay for the in vitro quantitative determination of immunoglobulin E in human serum and plasma.
Determination of total IgE is useful as an aid in the diagnosis of allergic diseases.
The electrochemiluminescence immunoassay “ECLIA” is intended for use on cobas e immunoassay analyzers.

Product Name	Cat. No.	Basic UDI-DI
IgE CalSet	11930427122	761333600742AQ

Intended Use:

IgE CalSet is used for calibrating the quantitative Elecsys IgE 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

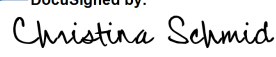
NB Ident. No.:

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

Mannheim, 30 March 2023

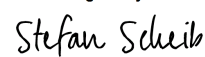
Roche Diagnostics GmbH

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

DocuSigned by:

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

Contact address:

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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 IGF-1	07475896190	761333600465AM
Elecsys IGF-1	07475918190	761333600466AP

Intended Use:

Immunoassay for the in vitro quantitative determination of insulin-like growth factor-1 (IGF-1) in human serum and plasma. The IGF-1 determination is intended to be used as an aid in the assessment of growth disorders in conjunction with other clinical and laboratory findings.

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

Product Name	Cat. No.	Basic UDI-DI
CalSet IGF-1	07475969190	761333600467AR

Intended Use:

CalSet IGF-1 is used for calibrating the quantitative Elecsys IGF-1 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, 11 October 2024

Roche Diagnostics GmbH

i.V./on behalf of the company

ppa./on behalf of the company

DocuSigned by:

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Dr. Klaus Riebel
Network Lead Site Head Penzberg & Cape Town

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Dr. Stefan Scheib
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