

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
ISE Cleaning Solution / Elecsys SysClean	11298500316	761333601595BA

Intended Use:

For the cleaning of ISE units on Roche/Hitachi analyzers.
 For the cleaning of 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
☐ 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, 11 July 2023

Roche Diagnostics GmbH

i.V./on behalf of the company

DocuSigned by:
Christina Schmid
E3965E80F3E840E...

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

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Product Name	Cat. No.	Basic UDI-DI
ISE Diluent Gen.2	04522630190	761333601279AV
ISE Diluent Gen.2	04880480190	761333601333AA
ISE Diluent Gen.2	04880480214	761333602620AP

Intended Use:

ISE Diluent Gen.2 is intended for diluting samples on the cobas c ISE analytical unit for the quantitative determination of sodium, potassium, and chloride in human origin serum, plasma or urine.

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

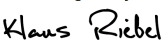
Certificates:☐ EU QM Certificate No.:☐ EU Technical Documentation Assessment Certificate No. (Class D, Near-Patient Testing, Self-Testing and Companion Diagnostics):**Other:**☐ Common Specifications:**Notified Body (NB) Name:** N/A**NB Address:** N/A**NB Ident. No.:** N/A

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Mannheim, 11 December 2024

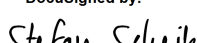
Roche Diagnostics GmbH

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

ppa./on behalf of the company

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Global Head of Regulatory Affairs, Core Lab

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Product Name	Cat. No.	Basic UDI-DI
ISE Internal Standard Gen.2	04522320190	761333600651AL
ISE Internal Standard Gen.2	04880455190	761333600663AT

Intended Use:

The ISE Internal Standard Gen.2 is intended for the monitoring of electrode potential on cobas c ISE analytical unit for the quantitative determination of sodium, potassium, and chloride in human origin serum, plasma or urine.

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, 3 May 2024

Roche Diagnostics GmbH

i.V./on behalf of the company

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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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Address: Sandhofer Strasse 116
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Single Registration Number: DE-MF-000006260

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Product Name	Cat. No.	Basic UDI-DI
ISE Reference Electrolyte	08392013190	761333600687B9
ISE Reference Electrolyte	11360981216	761333600718AT
ISE Reference Electrolyte	10820652216	761333600706AL

Intended Use:

The ISE Reference Electrolyte is intended for closing the measurement circuit on the cobas c ISE analytical unit for the quantitative determination of sodium, potassium, and chloride in human origin serum, plasma or urine.

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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☐ EU Technical Documentation Assessment Certificate No. (Class D, Near-Patient Testing, Self-Testing and Companion Diagnostics):

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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
ISE Standard High	11183982216	761333600711AD

Intended Use:

ISE Standard High is for use in the calibration of Ion Selective Electrodes on cobas c 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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☐ EU Technical Documentation Assessment Certificate No. (Class D, Near-Patient Testing, Self-Testing and Companion Diagnostics):

Other: ☐ Common Specifications:

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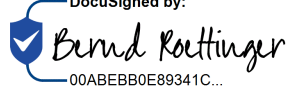
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Mannheim, 3 May 2024

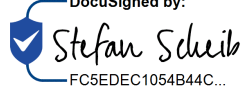
Roche Diagnostics GmbH

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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
ISE Standard Low	11183974216	761333600709AS

Intended Use:

ISE Standard Low is for use in the calibration of Ion Selective Electrodes on cobas c 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

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Other: ☐ Common Specifications:

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NB Address: Ridlerstraße 65
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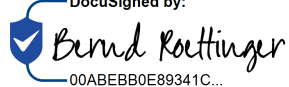
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Mannheim, 3 May 2024

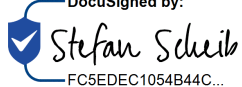
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Product Name	Cat. No.	Basic UDI-DI
LDHI2	03004732122	7613336001039G

Intended Use:

In vitro test for the quantitative determination of lactate dehydrogenase in human serum and plasma on cobas c and COBAS INTEGRA systems.

Product Name	Cat. No.	Basic UDI-DI
LDHI2	05401674190	761333600089AF

Intended Use:

In vitro test for the quantitative determination of lactate dehydrogenase in human serum and plasma on the cobas c 111 system.

Product Name	Cat. No.	Basic UDI-DI
LDHI2	05169330190	7613336000369S
LDHI2	05169330214	761333600722AJ
LDHI2	08057958190	761333600532AB
LDHI2	08057958214	761333602613AS

Intended Use:

In vitro test for the quantitative determination of lactate dehydrogenase in human serum and plasma on cobas c systems.

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 December 2024

Roche Diagnostics GmbH

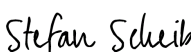
i.V./on behalf of the company

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

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
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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
NaCl Diluent 9%	04774230190	761333601318AE

Intended Use:

NaCl Diluent 9% is used as a sample diluent in conjunction with assay reagents on the cobas c 111 system.

Product Name	Cat. No.	Basic UDI-DI
NACL	04489357190	761333601272AF
NACL	05172152190	761333601357AQ
NACL	05172152214	761333601358AS
NACL	08063494190	761333601536AS
NACL	08063494214	761333602592BB

Intended Use:

Diluent NaCl 9 % is used as a sample diluent in conjunction with assay reagents on cobas c systems.

Product Name	Cat. No.	Basic UDI-DI
NaCl Diluent 9%	20756350322	761333601659BB

Intended Use:

NaCl Diluent 9% is used as a sample diluent in conjunction with assay reagents on COBAS INTEGRA 400 plus 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
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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: N/A

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, 29 August 2024

Roche Diagnostics GmbH

ppa./on behalf of the company

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485913ABEB04408...

Dr. Peer Lorenz
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Global Head of Regulatory Affairs, Core Lab

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Product Name	Cat. No.	Basic UDI-DI
Cell Wash Solution I/NaOH-D	04880285190	761333601329AK
Cell Wash Solution I/NaOH-D	04880285214	761333602619B6
Cell Wash Solution I/NaOH-D	07531869190	761333601496B7

Intended Use:

Cell Wash Solution I / NaOH-D is used as alkaline wash solution for reaction cells on Roche/Hitachi systems.

Product Name	Cat. No.	Basic UDI-DI
Basic Wash	08302545190	761333601544AR
Basic Wash	08453209190	761333602390AV

Intended Use:

Basic Wash is used as alkaline wash solution for reaction cells and for sample probes on the cobas c 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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☐ EU Technical Documentation Assessment Certificate No. (Class D, Near-Patient Testing, Self-Testing and Companion Diagnostics):

Other: ☐ Common Specifications:

Notified Body (NB) Name: N/A
NB Address:

NB Ident. No.: N/A

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

Mannheim, 16 February 2023

Roche Diagnostics GmbH

i.V./on behalf of the company

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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
NaOHD	04489241190	761333601271AD
NaOHD	05172128190	761333601353AG
NaOHD	05172128214	761333601354AJ
NaOHD	08063451190	761333601534AN

Intended Use:

Wash solution for reagent probes and reaction cells on cobas c systems.

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:

Notified Body (NB) Name: N/A
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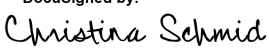
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Mannheim, 10 August 2023

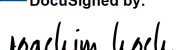
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Head of Pre-Market Quality Core Lab

i.V./on behalf of the company

DocuSigned by:

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Dr. Joachim Hoch
Subchapter Lead Global Regulatory Affairs

Contact address:

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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
Ammonia/Ethanol/CO ₂ Calibrator	20751995190	761333600773B3

Intended Use:

Ammonia/Ethanol/CO₂ Calibrator is for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the value sheets

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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Other: ☐ Common Specifications:

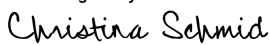
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NB Address: Ridlerstraße 65
 80339 Munich
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NB Ident. No.: 0123

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

Mannheim, 12 July 2023

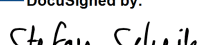
Roche Diagnostics GmbH

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
NH3L	05401739190	761333600092A4

Intended Use:

Enzymatic in vitro test for the quantitative determination of ammonia in human plasma on the cobas c 111 system.

Product Name	Cat. No.	Basic UDI-DI
NH3L	20766682322	761333600167AA

Intended Use:

In vitro test for the quantitative determination of the ammonia concentration in human plasma on COBAS INTEGRA systems.

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

ppa./on behalf of the company

DocuSigned by:
 Klaus Riebel
5E57330EEFE04C4...

DocuSigned by:
 Stefan Scheib
FC5EDEC1054B44C...

Dr. Klaus Riebel
Site Quality Head / Network Lead Penzberg

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
Ammonia/Ethanol/CO2 Control A	20753009190	761333600776B9

Intended Use:

Ammonia/Ethanol/CO2 Control Abnormal is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheets

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:

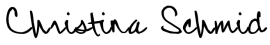
Notified Body (NB) Name: TÜV Süd Product Service GmbH
NB Address: Ridlerstraße 65
 80339 Munich
 Germany
NB Ident. No.: 0123

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

Mannheim, 12 July 2023

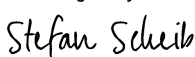
Roche Diagnostics GmbH

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
Ammonia/Ethanol/CO2 Control N	20752401190	761333600775B7

Intended Use:

Ammonia/Ethanol/CO2 Control Normal is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheets.

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:

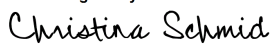
Notified Body (NB) Name: TÜV Süd Product Service GmbH
NB Address: Ridlerstraße 65
 80339 Munich
 Germany
NB Ident. No.: 0123

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

Mannheim, 12 July 2023

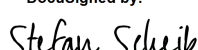
Roche Diagnostics GmbH

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

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: 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 ClinChem Multi 1**

Art.-Nr./Id. No.: **05947626, 05117003, 05117208**

Beschreibung/Description: PreciControl ClinChem Multi 1 wird in der Qualitätskontrolle zur Richtigkeits- und Präzisionskontrolle von den in den Wertebüchern angegebenen quantitativen Methoden eingesetzt.
PreciControl ClinChem Multi 1 is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheets.

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.

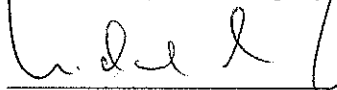
to which this declaration relates fulfils the requirements of EC Directive 98/79/EC of the Council of 27 October 1998 (and its relevant transposition into the national laws of the Member States in which the device is intended to be placed on the market) concerning in-vitro diagnostic devices.

Mannheim, 13. August 2010

Roche Diagnostics GmbH

for/on behalf of the company

i. V. on behalf of the company


Dr. M. Thein

Head of Quality & Regulatory
Management
Professional Diagnostics


A. Schenkel

Head of Quality Control
Professional Diagnostics

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

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

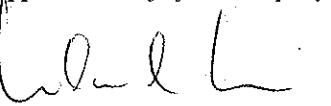
Die Roche Diagnostics GmbH erklärt, dass das Produkt/die Produktfamilie (bei rezepturgleichen Produkten)
Roche Diagnostics GmbH declares that the product/the product line (in case of products manufactured by identical recipes)

Produktname/Product name: **PreciControl ClinChem Multi 2**
Art.-Nr./Id. No.: **05947774, 05117216, 05117291**
Beschreibung/Description: PreciControl ClinChem Multi 2 wird in der Qualitätskontrolle zur Richtigkeits- und Präzisionskontrolle von den in den Wertebögen angegebenen quantitativen Methoden eingesetzt.
PreciControl ClinChem Multi i2 is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheets.

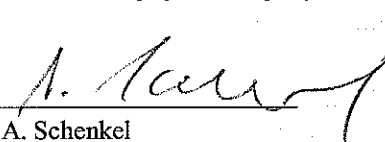
auf das/die sich diese Erklärung bezieht, den Forderungen der EG-Richtlinie 98/79/EG des Rates vom 27. Oktober 1998 (bzw. seine Umsetzung in nationales Recht der Mitgliedsstaaten in welchen das Produkt vermarktet werden soll) über In-vitro-Diagnostica entspricht.
to which this declaration relates fulfils 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, 13. August 2010

Roche Diagnostics GmbH
ppa./on behalf of the company i. V./on behalf of the company



Dr. M. Thein
Head of Quality & Regulatory
Management
Professional Diagnostics



A. Schenkel
Head of Quality Control
Professional Diagnostics

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

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
PHOS2	03183793122	7613336002099Z

Intended Use:

In vitro test for the quantitative determination of phosphorus in human serum, plasma and urine on cobas c and COBAS INTEGRA systems.

Product Name	Cat. No.	Basic UDI-DI
PHOS2	05171377190	7613336000389W
PHOS2	05171377214	7613336000419K
PHOS2	08058610190	7613336000139E

Intended Use:

In vitro test for the quantitative determination of phosphorus in human serum, plasma and urine on cobas c systems.

Product Name	Cat. No.	Basic UDI-DI
PHOS2	05401780190	761333600095AA

Intended Use:

In vitro test for the quantitative determination of the inorganic phosphate concentration in human serum, plasma and urine on the cobas c 111 system.

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, 13 September 2023

Roche Diagnostics GmbH

i.V./on behalf of the company

DocuSigned by:

00ABEBB0E89341C...

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

ppa./on behalf of the company

DocuSigned by:

FC5EDEC1054B44C...

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

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

EU Declaration of Conformity

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

Manufacturer: Roche Diagnostics GmbH

Address: Sandhofer Strasse 116
68305 Mannheim
Germany

Single Registration Number: DE-MF-000006260

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

Product Name	Cat. No.	Basic UDI-DI
Sample Cleaner 1	04708725190	761333601305A5
Sample Cleaner 1	05352991190	761333601362AH

Intended Use:

Wash solution for sample probes on Roche/Hitachi cobas c systems.

Product Name	Cat. No.	Basic UDI-DI
CLEAN	04774248190	761333601319AG

Intended Use:

Wash solution for Extra wash cycles for the reagent/sample probe on the cobas c 111 analyzer.

Product Name	Cat. No.	Basic UDI-DI
CLEAN	20764337322	761333601668BC

Intended Use:

Wash solution for Extra Wash Cycles for sample/reagent probes on the COBAS INTEGRA 400 plus analyzer.

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: N/A

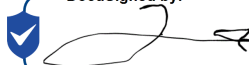
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to which this declaration relates fulfils the requirements of Regulation EU 2017/746 on in-vitro diagnostic medical devices.

Mannheim, 28 August 2024

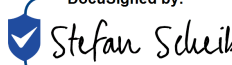
Roche Diagnostics GmbH

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

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
SMS	04489225190	761333601270AB
SMS	05172136190	761333601355AL
SMS	05172136214	761333601356AN
SMS	08063478190	761333601535AQ

Intended Use:

Wash solution for reagent probes and reaction cells on cobas c systems.

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:

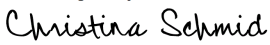
NB Ident. No.: N/A

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

Mannheim, 10 August 2023

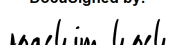
Roche Diagnostics GmbH

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:

18F3891ABF554FF...

Dr. Joachim Hoch
Subchapter Lead Global Regulatory Affairs

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
TP2	05171385190	7613336000449R
TP2	05171385214	761333600724AN
TP2	08058652190	7613336000169L
TP2	08058652214	761333602612AQ

Intended Use:

In vitro test for the quantitative determination of total protein in human serum and plasma on cobas c systems.

Product Name	Cat. No.	Basic UDI-DI
TP2	03183734190	7613336002079V

Intended Use:

In vitro test for the quantitative determination of total protein in human serum and plasma on cobas c and COBAS INTEGRA systems.

Product Name	Cat. No.	Basic UDI-DI
TP2	04657586190	761333600297AQ

Intended Use:

In vitro test for the quantitative determination of total protein in human serum and plasma on the cobas c 111 system.

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, 10 October 2024

Roche Diagnostics GmbH

i.V./on behalf of the company

ppa./on behalf of the company

DocuSigned by:

5E57330EEFE04C4...

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

DocuSigned by:

FC5EDEC1054B44C...

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

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

**EG-Konformitätserklärung/EC Declaration of Conformity**

gemäß Anhang III der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998
as per Annex III of Directive 98/79/EC of the European Parliaments and Council of 27 October 1998

Hersteller/Manufacturer: Roche Diagnostics GmbH

Adresse/Address: Roche Centralized 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: UREAL
Urea/BUN

Art.-Nr./Id. No.: 04460715

Beschreibung/Description (1): In vitro Test zur quantitativen Bestimmung der Harnstoff/
BUN (Blutharnstickstoff)-Konzentration in Humanserum, -plasma
und -urin mit COBAS INTEGRA Systemen.
*In vitro test for the quantitative determination of the urea/BUN (blood
urea nitrogen) concentration in human serum, plasma and urine on
COBAS INTEGRAC systems.*

Beschreibung/Description (2): In vitro Test zur quantitativen Bestimmung von Harnstoff/
Harnstickstoff in Humanserum, -plasma und -urin mit
Roche/Hitachi cobas c Systemen.
*In vitro test for the quantitative determination of urea/urea nitrogen
in human serum, plasma and urine on Roche/Hitachi
cobas c systems.*

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, 09.08.2006

Roche Diagnostics GmbH

ppa./on behalf of the company

Dr. M. Thein
Head of Quality Management &
Regulatory Affairs
Centralized Diagnostics

i. V./on behalf of the company

A. Schenkel
Head of Quality Assurance
Centralized Diagnostics

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

ureal_neu.doc-AJ