

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
A1C-3	05336163190	7613336000739Y

Intended Use:

In vitro test for the quantitative determination of mmol/mol hemoglobin A1c (IFCC) and % hemoglobin A1c (DCCT/NGSP) in whole blood or hemolysate on cobas c and COBAS INTEGRA systems. HbA1c determinations are useful monitoring of long-term blood glucose control in individuals with diabetes mellitus. Moreover, this test is to be used as an aid in diagnosis of diabetes and identifying patients who may be at risk for developing diabetes

Product Name	Cat. No.	Basic UDI-DI
A1C-3	05336180190	761333600075A4

Intended Use:

In vitro test for the quantitative determination of mmol/mol hemoglobin A1c (IFCC) and % hemoglobin A1c (DCCT/NGSP) in whole blood and hemolysates prepared from whole blood on the cobas c 111 system. HbA1c determinations are useful for monitoring of long-term blood glucose control in individuals with diabetes mellitus. Moreover, this test is to be used as an aid in diagnosis of diabetes and identifying patients who may be at risk for developing diabetes.

Product Name	Cat. No.	Basic UDI-DI
A1CX3	07559674190	761333600479AY
A1CX3	08056668190	7613336005009W
A1CX3	08445699190	7613336001189V

Intended Use:

In vitro test for the quantitative determination of mmol/mol hemoglobin A1c (IFCC) and % hemoglobin A1c (DCCT/NGSP) in whole blood or hemolysate on cobas c systems. HbA1c determinations are useful for monitoring of long-term blood glucose control in individuals with diabetes mellitus. Moreover, this test is to be used as an aid in diagnosis of diabetes and identifying patients who may be at risk for developing diabetes.

Product Name	Cat. No.	Basic UDI-DI
PreciControl HbA1c norm	05479207190	761333600099AJ
PreciControl HbA1c norm	05991323922	761333600172A3

Intended Use:

PreciControl HbA1c norm is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheets.

Product Name	Cat. No.	Basic UDI-DI
PreciControl HbA1c path	05912504190	761333600375AK
PreciControl HbA1c path	05991331922	761333600173A5

Intended Use:

PreciControl HbA1c path is for use in quality control by monitoring accuracy and precision for the quantitative methods as specified in the value sheets.

Product Name	Cat. No.	Basic UDI-DI
C.f.a.s. HbA1c	04528417190	761333600282AB

Intended Use:

C.f.a.s. (Calibrator for automated systems) HbA1c is for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the enclosed 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:

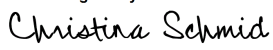
Notified Body (NB) Name: TÜV Süd Product Service GmbH
 NB Address: Ridlerstraße 65
 80339 Munich
 Germany
 NB Ident. No.: 0123

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

Mannheim, 19 February 2024

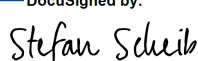
Roche Diagnostics GmbH

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: 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: **A1CD**
Hemolyzing reagent

Art.-Nr./Cat. No.: **08463107190**

Beschreibung/Description: Das Hämolysereagenz dient als Diluent für den Tina-quant Hemoglobin A1c Gen.3 Test auf **cobas c** Systemen.
*The hemolyzing reagent is used as diluent for the Tina-quant Hemoglobin A1c Gen.3 assay on **cobas c** systems.*

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, 9 November 2018

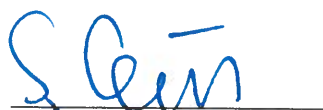
Roche Diagnostics GmbH

ppa./on behalf of the company



Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions

ppa./on behalf of the company



Dr. 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

EG-Konformitätserklärung/EC Declaration of Conformity

gemäß Anhang III der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998
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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: **Acid Wash**

Art.-Nr./Cat. No.: **08302723190**

Beschreibung/Description: Acid Wash wird als saure Waschlösung für Reagenzküvetten auf
Roche/Hitachi **cobas c** Systemen verwendet.

*Acid Wash is used as acid wash solution for reaction cells on the
Roche/Hitachi **cobas c** 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.

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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, 7 November 2018

Roche Diagnostics GmbH

ppa./on behalf of the company
ppa. Dr. Beate Bonefeld



Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions

ppa./on behalf of the company



Dr. Stefan Scheib
Director Global Regulatory Affairs
Centralised and Point of Care Solutions

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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
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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: **ALB2**
Albumin Gen.2

Art.-Nr./Cat. No.: **08056692190**

Beschreibung/Description: In-vitro-Test zur quantitativen Bestimmung von Albumin in
Humanserum und -plasma mit Roche/Hitachi **cobas c** Systemen.
*In vitro test for the quantitative determination of albumin in human
serum and plasma on Roche/Hitachi **cobas c** systems.*

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.
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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, 16 November 2018

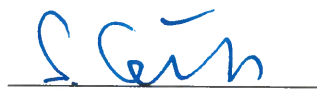
Roche Diagnostics GmbH

ppa./on behalf of the company

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Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions



Dr. Stefan Scheib
Director Global Regulatory Affairs
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D-68305 Mannheim

EG-Konformitätserklärung/EC Declaration of Conformity

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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: **ALP2**
Alkaline phosphatase acc. to IFCC Gen.2

Art.-Nr./Cat. No.: **08056757190**

Beschreibung/Description: In-vitro-Test zur quantitativen Bestimmung der alkalischen
Phosphatase in Humanserum und -plasma mit Roche/Hitachi **cobas c**
Systemen.

*In vitro test for the quantitative determination of alkaline phosphatase
in human serum and plasma on Roche/Hitachi **cobas c** systems.*

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.

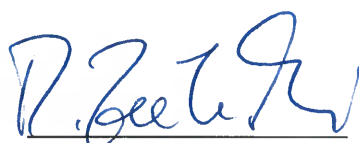
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Council of 27 October 1998 on in-vitro diagnostic medical devices (and its relevant transposition into the
national laws of the Member States in which the device is intended to be placed on the market).*

Mannheim, 22 October 2018

Roche Diagnostics GmbH

ppa./on behalf of the company

ppa./on behalf of the company



Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions



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

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
ALTP2	07049480190	761333600623AF
ALTP2	08104697190	761333600646AT
ALTP2	08104697214	761333602943BJ

Intended Use:

In vitro test for the quantitative determination of alanine aminotransferase (ALT) with pyridoxal phosphate activation 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, 10 October 2024

Roche Diagnostics GmbH

i.V./on behalf of the company

ppa./on behalf of the company

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

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

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: **AMYL2**
 α -Amylase EPS ver.2

Art.-Nr./Cat. No.: **08056811190**

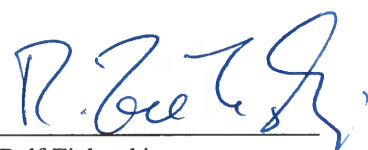
Beschreibung/Description: In-vitro-Test zur quantitativen Bestimmung der α -Amylase in
Humanserum, -plasma und -urin mit Roche/Hitachi **cobas c** Systemen.
*In vitro test for the quantitative determination of α -amylase in human
serum, plasma and urine on Roche/Hitachi **cobas c** systems.*

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, 22 October 2018

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. 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

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
AMY-P	05167035190	761333600327A8
AMY-P	08056820190	761333600508AE

Intended Use:

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

Product Name	Cat. No.	Basic UDI-DI
AMY-P	20766623322	761333600165A6

Intended Use:

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

Product Name	Cat. No.	Basic UDI-DI
AMY-P	05401771190	761333600094A8

Intended Use:

In vitro test for the quantitative determination of pancreatic α -amylase 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, 14 June 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:

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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
ASLOT	04489403190	761333600268AH
ASLOT	05219191190	7613336000639V
ASLOT	08105472190	7613336000529Q

Intended Use:

In vitro test for the quantitative immunological determination of antistreptolysin O 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
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Certificates:

- ☒ EU QM Certificate No.: V12 010283 0639
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Other: ☐ Common Specifications:

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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, 21 November 2023

Roche Diagnostics GmbH

i.V./on behalf of the company

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

ppa./on behalf of the company

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

Contact address:

Roche Diagnostics GmbH
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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
ASTP2	07049625190	761333600624AH
ASTP2	08104719190	761333600647AV
ASTP2	08104719214	761333602922BA

Intended Use:

In vitro test for the quantitative determination of aspartate aminotransferase (AST) with pyridoxal phosphate activation 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
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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, 10 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

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

EG-Konformitätserklärung/EC Declaration of Conformity

gemäß Anhang III der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998
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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: **Basic Wash**

Art.-Nr./Cat. No.: **08302545190**

Beschreibung/Description: Basic Wash wird als alkalische Waschlösung für Reagenzküvetten auf
Roche/Hitachi **cobas c** Systemen verwendet.

*Basic Wash is used as alkaline wash solution for reaction cells on the
Roche/Hitachi **cobas c** analyzers.*

auf das/die sich diese Erklärung bezieht, den Forderungen der Richtlinie 98/79/EG des Europäischen Parlaments und
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Mannheim, 7 November 2018

Roche Diagnostics GmbH

ppa./on behalf of the company
ppa. Dr. Beate Bonefeld



Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions

ppa./on behalf of the company



Dr. Stefan Scheib
Director Global Regulatory Affairs
Centralised and Point of Care Solutions

Kontaktadresse/Contact address: Roche Diagnostics GmbH
Abt./Dept. Global Regulatory Affairs
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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: **BILD2**
Bilirubin Direct Gen.2 (Jendrassik-Grof)
Bilirubin Direct Gen.2 (Dumas standardization)

Art.-Nr./Cat. No.: **08056951190**

Beschreibung/Description: In-vitro-Test zur quantitativen Bestimmung von direktem Bilirubin in
Humanserum und -plasma mit Roche/Hitachi **cobas c** Systemen.
*In vitro test for the quantitative determination of direct bilirubin in
human serum and plasma on Roche/Hitachi cobas c systems.*

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, 16 November 2018

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. 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

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: **BILT3**
Bilirubin Total Gen.3
Art.-Nr./Cat. No.: **08056960190**
Beschreibung/Description: In-vitro-Test zur quantitativen Bestimmung von Gesamtbilirubin in Serum und Plasma von Erwachsenen und Neugeborenen mit Roche/Hitachi **cobas c** Systemen.
In vitro test for the quantitative determination of total bilirubin in serum and plasma of adults and neonates on Roche/Hitachi cobas c systems.

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, 16 November 2018

Roche Diagnostics GmbH

ppa./on behalf of the company



Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions



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

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: **CA2**
Calcium Gen.2

Art.-Nr./Cat. No.: **08057427190**

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

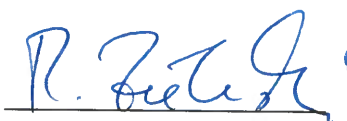
auf das/die sich diese Erklärung bezieht, den Forderungen der Richtlinie 98/79/EG des Europäischen Parlaments und
des Rates vom 27. Oktober 1998 über In-vitro-Diagnostica (bzw. seine Umsetzung in nationales Recht der
Mitgliedsstaaten in welchen das Produkt vermarktet werden soll) entspricht.
*to which 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, 16 November 2018

Roche Diagnostics GmbH

ppa./on behalf of the company

ppa./on behalf of the company



Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions



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

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

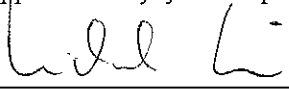
Hersteller/Manufacturer: Roche Diagnostics GmbH
Adresse/Address: Roche Centralized Diagnostics
 Sandhofer Straße 116
 D-68305 Mannheim

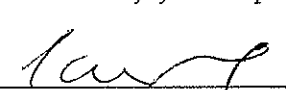
Die Roche Diagnostics GmbH erklärt, dass das Produkt/die Produktfamilie (bei rezepturgleichen Produkten)
Roche Diagnostics GmbH declares that the product/the product line (in case of products manufactured by identical recipes)

Produktname/Product name: C.f.a.s. HbA1c
Art.-Nr./Id. No.: 04528417
Beschreibung/Description: C.f.a.s. (Calibrator for automated systems) HbA1c wird zur Kalibration von quantitativen Roche-Methoden an klinisch-chemischen Analysenautomaten von Roche wie im beiliegenden Werteblatt angegeben verwendet.
C.f.a.s. (Calibrator for automated systems) HbA1c is for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers as specified in the enclosed value sheet.

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, 14.10.2005
 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

Roche Diagnostics GmbH

Roche Centralized Diagnostics
 Sandhofer Strasse 116
 D-68305 Mannheim
 Telefon +49-621-759 0
 Telefax +49-621-759 20 90

Registergericht Mannheim
 HRB 3962
 Aufsichtsrat:
 Dr. Franz B. Humer, Vorsitzender

cfashba1c.doc-AJ

Geschäftsführung:
 Dr. Jürgen Schwiezer, Vorsitzender
 Dr. Manfred Baier, Staffan Ek,
 Dr. Volker Pfahlert,
 Burkhard G. Piper,
 Peter-Claus Schiller,
 Prof. Dr. Dr. Klaus Strein

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: **C.f.a.s. Lipids**

Art.-Nr./Id. No.: **12172623**

Beschreibung/Description: C.f.a.s. (Calibrator for automated systems) Lipids wird zur Kalibration von
quantitativen Roche-Methoden an klinisch-chemischen Analysenautomaten
*C.f.a.s. (Calibrator for automated systems) Lipids is for use in the
calibration of quantitative Roche methods on Roche clinical chemistry
analyzers as specified in the value sheets.*

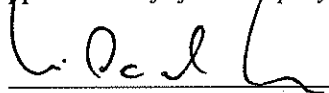
auf das/die sich diese Erklärung bezieht, den Forderungen der EG-Richtlinie 98/79/EG des Rates vom
27. Oktober 1998 (bzw. seine Umsetzung in nationales Recht der Mitgliedsstaaten in welchen das Produkt
vermarktet werden soll) über In-vitro-Diagnostica entspricht.
*to which this declaration relates fulfils 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, 13.07.2011

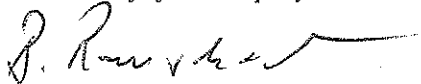
Roche Diagnostics GmbH

for/on behalf of the company

i. V. on behalf of the company



Dr. M. Thein
Head of Quality
Roche Professional Diagnostics



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

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

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
C.f.a.s. PAC	03555941190	761333600600A3

Intended Use:

C.f.a.s. (Calibrator for automated systems) PAC (Prealbumin-ASLO-Ceruloplasmin) 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
- ☐ 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:

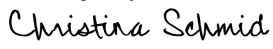
Notified Body (NB) Name: TÜV Süd Product Service GmbH
NB Address: Ridlerstraße 65
 80339 Munich
 Germany
NB Ident. No.: 0123

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

Mannheim, 12 July 2023

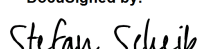
Roche Diagnostics GmbH

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
C.f.a.s Proteins	11355279160	761333600715AM
C.f.a.s Proteins	11355279216	761333600716AP

Intended Use:

C.f.a.s. (Calibrator for automated systems) Proteins 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
☐ 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:

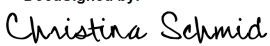
Notified Body (NB) Name: TÜV Süd Product Service GmbH
NB Address: Ridlerstraße 65
 80339 Munich
 Germany
NB Ident. No.: 0123

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

Mannheim, 12 July 2023

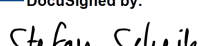
Roche Diagnostics GmbH

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: **Calibrator for automated systems**

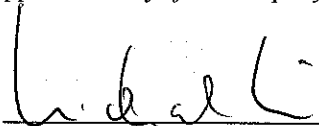
Art.-Nr./Id. No.: **10759350**

Beschreibung/Description:
Calibrator for automated systems (C.f.a.s.) wird zur Kalibration von quantitativen Roche-Methoden an klinisch-chemischen Analysengeräten von Roche wie in den Wertebllättern angegeben verwendet.
Calibrator for automated systems (C.f.a.s.) is for use in the calibration of quantitative Roche methods on Roche clinical chemistry analyzers 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.

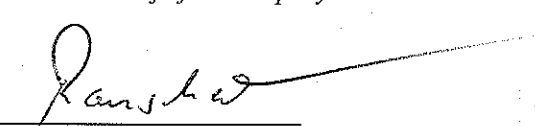
Mannheim, 26.10.2011

Roche Diagnostics GmbH
ppa./on behalf of the company



Dr. M. Thein
Head of Quality
Roche Professional Diagnostics

i. V./on behalf of the company



Dr. B. Rauschel
Head of Quality Control Penzberg
Roche 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 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: **CHOL2**
Cholesterol Gen.2

Art.-Nr./Cat. No.: **08057443190**

Beschreibung/Description: In-vitro-Test zur quantitativen Bestimmung von Cholesterin in
Humanserum und -plasma mit Roche/Hitachi **cobas c** Systemen.
*In vitro test for the quantitative determination of cholesterol in human
serum and plasma on Roche/Hitachi **cobas c** systems.*

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 November 2018

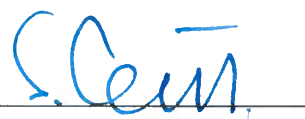
Roche Diagnostics GmbH

ppa./on behalf of the company



Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions

ppa./on behalf of the company



Dr. 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

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: Hitachi High-Tech Corporation
1-17-1 Toranomom, Minato-ku
Tokyo 105-6409
Japan

Authorized Representative: Roche Diagnostics GmbH
Sandhofer Strasse 116
68305 Mannheim
Germany

Die Roche Diagnostics GmbH erklärt, dass das Produkt/die Produktfamilie
Roche Diagnostics GmbH declares that the product/the product line

Produktname/Product name: **cobas® pure integrated solutions**

Art.-Nr./Id. No.: **siehe Seite 2 / see page 2**

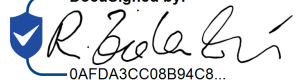
Beschreibung/Description: The **cobas® pure** integrated solutions is an in-vitro IVD device used for the quantitation of clinical chemistry / immunochemistry and Ion Selective Electrolyte parameters from various biological fluids.

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, 9 März 2021

Roche Diagnostics GmbH

ppa./on behalf of the company

DocuSigned by:

0AFDA3CC08B94C8...

Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions

ppa./on behalf of the company

DocuSigned by:

FC5EDEC1054B44C...

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
68305 Mannheim
Germany

Liste der **cobas® pure** integrated solutions Systemkomponenten: /
*List of **cobas® pure** integrated solutions system components:*

Produktname / <i>Product Name</i>	Produkt Art. Nr. / <i>Product Id. No.</i>
cobas e 402 analytical unit	09031553001
cobas c 303 analytical unit	09031529001
sample supply unit	09031537001
Reaction Cell for c 303	09033408001
cobas pure liquid waste container	09033394001

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: 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: **CREJ2**
Creatinine Jaffe Gen.2

Art.-Nr./Cat. No.: **08057532190**

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

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, 16 November 2018

Roche Diagnostics GmbH

ppa./on behalf of the company

ppa./on behalf of the company



Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions



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

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
CRP4	07876033190	761333600633AJ

Intended Use:

Immunoturbidimetric assay for the in vitro quantitative determination of CRP in human serum and plasma on cobas c and COBAS INTEGRA systems.

Product Name	Cat. No.	Basic UDI-DI
CRP4	07876424190	761333600634AL
CRP4	08057591190	761333600639AW

Intended Use:

Immunoturbidimetric assay for the in vitro quantitative determination of CRP in human serum and plasma on cobas c systems.

Product Name	Cat. No.	Basic UDI-DI
CRP4	07876432190	761333600635AN

Intended Use:

Immunoturbidimetric assay for the in vitro quantitative determination of CRP 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:
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, 1 September 2023

Roche Diagnostics GmbH

i.V./on behalf of the company

ppa./on behalf of the company

DocuSigned by:

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

DocuSigned by:

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