

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:

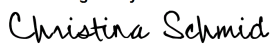
Notified Body (NB) Name: TÜV Süd Product Service GmbH
 NB Address: Ridlerstraße 65
 80339 Munich
 Germany
 NB Ident. No.: 0123

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

Mannheim, 19 February 2024

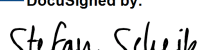
Roche Diagnostics GmbH

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:

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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: **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

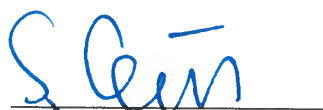
Roche Diagnostics GmbH

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

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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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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
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Mannheim, 16 November 2018

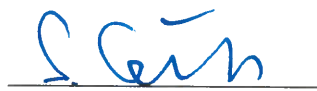
Roche Diagnostics GmbH

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

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D-68305 Mannheim

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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: **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.

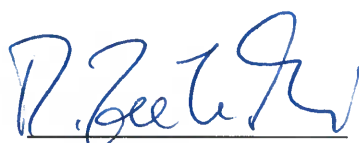
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Council of 27 October 1998 on in-vitro diagnostic medical devices (and its relevant transposition into the
national laws of the Member States in which the device is intended to be placed on the market).*

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

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

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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
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Produktname/Product name: **AMYL2**
 α -Amylase EPS ver.2

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

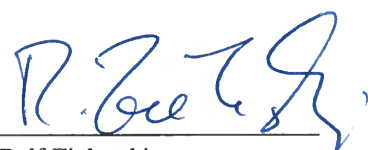
Beschreibung/Description: In-vitro-Test zur quantitativen Bestimmung der α -Amylase in
Humanserum, -plasma und -urin mit Roche/Hitachi **cobas c** Systemen.
*In vitro test for the quantitative determination of α -amylase in human
serum, plasma and urine on Roche/Hitachi **cobas c** systems.*

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

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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
☐ Technical Documentation Assessment Class B/C/D for Near-Patient Testing – Annex IX
☐ Technical Documentation Assessment Class C/D for Companion Diagnostics – Annex IX

Certificates: ☒ EU QM Certificate No.: V12 010283 0639
☐ EU Technical Documentation Assessment Certificate No. (Class D, Near-Patient Testing, Self-Testing and Companion Diagnostics):

Other: ☐ Common Specifications:

Notified Body (NB) Name: TÜV Süd Product Service GmbH

NB Address: Ridlerstraße 65
80339 Munich
Germany

NB Ident. No.: 0123

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Mannheim, 10 October 2024

Roche Diagnostics GmbH

i.V./on behalf of the company

ppa./on behalf of the company

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

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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
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, 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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Hersteller/Manufacturer: Roche Diagnostics GmbH

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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
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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

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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: **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.
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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
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Single Registration Number: DE-MF-000006260

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Product Name	Cat. No.	Basic UDI-DI
Elecsys CA 19-9	11776193122	761333600730AH
Elecsys CA 19-9	11776193214	761333602081AD
Elecsys CA 19-9	07027028190	761333600799BM
Elecsys CA 19-9	07027028214	761333602050A2

Intended Use:

Immunoassay for the in vitro quantitative determination of CA 19-9 in human serum and plasma. The electrochemiluminescence immunoassay “ECLIA” is intended for use on cobas e immunoassay analyzers.

Product Name	Cat. No.	Basic UDI-DI
CA 19-9 CalSet	11776215122	761333600732AM

Intended Use:

CA 19-9 CalSet is used for calibrating the quantitative Elecsys CA 19-9 assay on cobas e immunoassay analyzers.

Risk Class: ☐ A ☐ B ☒ C ☐ D

Conformity Route:

☐ Self-Declaration of Conformity (Class A)

☐ Self-Declaration of Conformity after Notified Body involvement for sterile manufacturing conditions acc. Art. 48 (10) (Class A sterile)

☒ Technical Documentation Assessment Class B/C – Annex IX

☐ Technical Documentation Assessment Class D – Annex IX

☐ Technical Documentation Assessment Class B/C/D for Self-Testing – Annex IX

☐ Technical Documentation Assessment Class B/C/D for Near-Patient Testing – Annex IX

☐ Technical Documentation Assessment Class C/D for Companion Diagnostics – Annex IX

Certificates:

☒ EU QM Certificate No.: V12 010283 0639

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

Other:

☐ Common Specifications:

Notified Body (NB) Name: TÜV Süd Product Service GmbH

NB Address: Ridlerstraße 65
80339 Munich
Germany

NB Ident. No.: 0123

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

Mannheim, 12 August 2024

Roche Diagnostics GmbH

ppa./on behalf of the company

DocuSigned by:

485913ABEB04408...

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

ppa./on behalf of the company

DocuSigned by:

FC5EDEC1054B44C...

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

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

EG-Konformitätserklärung/EC Declaration of Conformity

gemäß Anhang 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.*

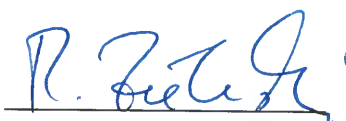
auf das/die sich diese Erklärung bezieht, den Forderungen der Richtlinie 98/79/EG des Europäischen Parlaments und
des Rates vom 27. Oktober 1998 über In-vitro-Diagnostica (bzw. seine Umsetzung in nationales Recht der
Mitgliedsstaaten in welchen das Produkt vermarktet werden soll) entspricht.
*to which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

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
CERU	05950848190	761333600382AG
CERU	08105553190	761333600059A6

Intended Use:

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

Product Name	Cat. No.	Basic UDI-DI
CERU	20764663322	7613336001609U

Intended Use:

In vitro test for the quantitative determination of ceruloplasmin in human serum and plasma on cobas c and 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:

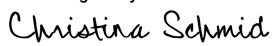
Notified Body (NB) Name: TÜV Süd Product Service GmbH
NB Address: Ridlerstraße 65
80339 Munich
Germany
NB Ident. No.: 0123

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

Mannheim, 21 February 2024

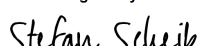
Roche Diagnostics GmbH

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
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