

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: **ALT**
Alanine aminotransferase acc. IFCC with or without pyridoxal phosphate activation

Art.-Nr./Cat. No.: **04718569190**

Beschreibung/Description: In-vitro-Test zur quantitativen Bestimmung der Alaninaminotransferase (ALT) mit oder ohne Pyridoxalphosphataktivierung in Humanserum und -plasma mit dem **cobas c 111** System.
In vitro test for the quantitative determination of alanine aminotransferase (ALT), with or without pyridoxal phosphate activation, in human serum and plasma on the cobas c 111 system.

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, 25 August 2017

Roche Diagnostics GmbH

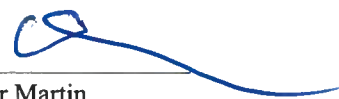
ppa./on behalf of the company

ppa. Dr. Lydia Langen



Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions

ppa./on behalf of the company



Dr. Peter Martin
Senior Director Global Regulatory Affairs
Centralised and Point of Care Solutions

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

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
BILD2	05168384190	7613336003309V
BILD2	05168384214	7613336003319X
BILD2	08056951190	7613336005109Z

Intended Use:

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

Product Name	Cat. No.	Basic UDI-DI
BILD2	05589061190	761333600343A6

Intended Use:

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

Product Name	Cat. No.	Basic UDI-DI
BILD2	05589134190	761333600344A8

Intended Use:

In vitro test for the quantitative determination of direct bilirubin 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, 6 December 2023

Roche Diagnostics GmbH

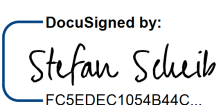
i.V./on behalf of the company

DocuSigned by:

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

ppa./on behalf of the company

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

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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
BILT3	05795397190	761333600348AG

Intended Use:

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

Product Name	Cat. No.	Basic UDI-DI
BILT3	05795419190	761333600349AJ
BILT3	08056960190	761333600511A3

Intended Use:

In vitro test for the quantitative determination of total bilirubin in serum and plasma of adults and neonates on cobas c systems.

Product Name	Cat. No.	Basic UDI-DI
BILT3	05795648190	761333600350A3

Intended Use:

In vitro test for the quantitative determination of total bilirubin in serum and plasma of adults and neonates 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 November 2023

Roche Diagnostics GmbH

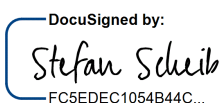
i.V./on behalf of the company

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

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

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EC 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
CLEAN	04774248190	761333601319AG
Sample Cleaner 1	05352991190	761333601362AH
CLEAN	20764337322	761333601668BC

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, 26 August 2021

Roche Diagnostics GmbH

ppa./on behalf of the company

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Ralf Zielenski
Head Q&R Compliance, PRRC RDG
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D-68305 Mannheim

EC 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: TBD (application filed; confirmation pending)

Authorized Representative: N/A
Address:

Single Registration Number: N/A

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

Product Name	Cat. No.	Basic UDI-DI
GGT-2	03002721122	7613336001029E
GGT-2	05168775190	7613336000229F
GGT-2	05168775214	7613336000259M
GGT-2	05401461190	761333600083A3
GGT-2	08057796190	761333600525AE

Risk Class: ☐ A ☒ B ☐ C ☐ D

Conformity Route:

- ☐ Self-Declaration of Conformity (Class A)
- ☒ 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.

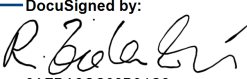
Mannheim, 20 April 2021

Roche Diagnostics GmbH

ppa./on behalf of the company

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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
GLUC2	04657527190	761333600943B4

Intended Use:

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

Product Name	Cat. No.	Basic UDI-DI
GLUC2	05882095190	761333600963BA
GLUC2	08106037190	7613336010089U

Intended Use:

In vitro test for the quantitative determination of glucose in human hemolysate on cobas c systems.

Product Name	Cat. No.	Basic UDI-DI
GLUC2	20767131322	761333601056A7

Intended Use:

In vitro test for the quantitative determination of glucose in human serum, plasma, urine, CSF and hemolysate 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:
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, 22 June 2023

Roche Diagnostics GmbH

i.V./on behalf of the company

ppa./on behalf of the company

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Global Head of Regulatory Affairs, Core Lab

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Manufacturer: Roche Diagnostics GmbH
Address: Sandhofer Strasse 116
 68305 Mannheim
 Germany

Single Registration Number: DE-MF-000006260

Authorized Representative: N/A
Address:

Single Registration Number: N/A

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

Product Name	Cat. No.	Basic UDI-DI
UREAL	04460715190	761333600264A9
UREAL	04657616190	7613336003009L
UREAL	05171873190	7613336000539S
UREAL	08058806190	7613336000249K
UREAL	05171873214	761333600958BH

Risk Class: ☐ A ☒ B ☐ C ☐ D

Conformity Route:

- ☐ Self-Declaration of Conformity (Class A)
- ☒ 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 June 2021

Roche Diagnostics GmbH

ppa./on behalf of the company

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Dr. Joachim Hoch
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