

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
Cell Wash Solution II / Acid Wash	04880307190	761333601331A6
Sample Cleaner 2	05958024190	761333601392AS
Sample Cleaner 2	05968828190	761333601396B2
Acid Wash	08302723190	761333601545AT

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

DocuSigned by:

A7F0BA9FE91A46A...

Ralf Zielenski
Head Q&R Compliance, PRRC RDG
Centralised and Point of Care Solutions

i.V./on behalf of the company

DocuSigned by:

18F3891ABF554FF...

Dr. Joachim Hoch
Director Global Regulatory Affairs
Centralised and Point of Care Solutions

Contact address:

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

CE 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
ALB2	03183688122	7613336002059R
ALB2	04657357190	761333600294AJ
ALB2	05166861190	7613336003229W
ALB2	08056692190	761333600502A2

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

i.V./on behalf of the company

DocuSigned by:

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Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions

DocuSigned by:

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Dr. Joachim Hoch
Director Global Regulatory Affairs
Centralised and Point of Care Solutions

Contact address:

Roche Diagnostics GmbH
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Sandhofer Strasse 116
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
ALP2	03333701190	7613336002329U
ALP2	03333752190	7613336002339W
ALP2	05166888190	7613336003239Y
ALP2	05166888214	761333600324A2
ALP2	08056757190	761333600505A8
ALP2S	04657373190	761333600295AL

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
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NB Ident. No.: 0123

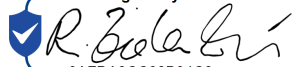
to which this declaration relates fulfils the requirements of Regulation EU 2017/746 on in-vitro diagnostic medical devices.

Mannheim, 25 March 2021

Roche Diagnostics GmbH

ppa./on behalf of the company

i.V./on behalf of the company

DocuSigned by:

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Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions

DocuSigned by:

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Dr. Joachim Hoch
Director Global Regulatory Affairs
Centralised and Point of Care Solutions

Contact address:

Roche Diagnostics GmbH
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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
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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
ALTL	20764957322	761333600163A2
ALT	05850797190	761333600363AC
ALTL	04718569190	7613336003029Q
ALTLP	04467388190	761333600265AB
ALTPM	05531462190	761333600338AD
ALTP	08056773190	761333600506AA

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
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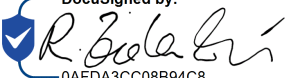
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Mannheim, 20 April 2021

Roche Diagnostics GmbH

ppa./on behalf of the company

i.V./on behalf of the company

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Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions

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 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
AMYL2	03183742122	7613336002089X
AMYL2	05167027190	761333600325A4
AMYL2	05167027214	761333600326A6
AMYL2	05401496190	761333600085A7
AMYL2	08056811190	761333600507AC

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
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NB Ident. No.: 0123

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

Mannheim, 31 May 2021


Roche Diagnostics GmbH

ppa./on behalf of the company

i.V./on behalf of the company

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 *Ralf Zielenski*
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Ralf Zielenski
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DocuSigned by:
 **Joachim Hoch**
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Dr. Joachim Hoch
Director Global Regulatory Affairs
Centralised and Point of Care Solutions

Contact address:

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 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
AST	05850819190	761333600364AE
ASTL	04657543190	761333600296AN
ASTL	20764949322	7613336001629Y
ASTLP	04467493190	761333600266AD
ASTPM	05531446190	761333600337AB
ASTP	08056838190	761333600509AG

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
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NB Ident. No.: 0123

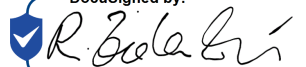
to which this declaration relates fulfils the requirements of Regulation EU 2017/746 on in-vitro diagnostic medical devices.

Mannheim, 5 May 2021

Roche Diagnostics GmbH

ppa./on behalf of the company

i.V./on behalf of the company

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Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions

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Dr. Joachim Hoch
Director Global Regulatory Affairs
Centralised and Point of Care Solutions

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Roche Diagnostics GmbH
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D-68305 Mannheim

EC Declaration of Conformity

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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
BILD2	05168384190	7613336003309V
BILD2	05168384214	7613336003319X
BILD2	05589061190	761333600343A6
BILD2	05589134190	761333600344A8
BILD2	08056951190	7613336005109Z

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:

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

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Notified Body (NB) Name: TÜV Süd Product Service GmbH
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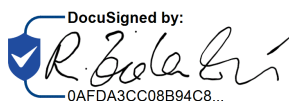
to which this declaration relates fulfils the requirements of Regulation EU 2017/746 on in-vitro diagnostic medical devices.

Mannheim, 20 April 2021

Roche Diagnostics GmbH

ppa./on behalf of the company

i.V./on behalf of the company

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Ralf Zielenski
Head of Quality
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DocuSigned by:

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Dr. Joachim Hoch
Director Global Regulatory Affairs
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Contact address:

Roche Diagnostics GmbH
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Sandhofer Strasse 116
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
BILT3	05795397190	761333600348AG
BILT3	05795419190	761333600349AJ
BILT3	05795648190	761333600350A3
BILT3	08056960190	761333600511A3

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
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NB Ident. No.: 0123

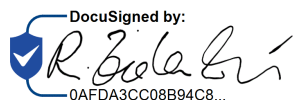
to which this declaration relates fulfils the requirements of Regulation EU 2017/746 on in-vitro diagnostic medical devices.

Mannheim, 23 April 2021

Roche Diagnostics GmbH

ppa./on behalf of the company

i.V./on behalf of the company

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Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions

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Dr. Joachim Hoch
Director Global Regulatory Affairs
Centralised and Point of Care Solutions

Contact address:

Roche Diagnostics GmbH
Abt./Dept. Global Regulatory Affairs
Sandhofer Strasse 116
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
CKMB	05168562190	7613336000069H
CKMB	07190808190	761333600435AC
CKMB	07442050190	761333600459AS
CKMB	08057486190	761333600516AD
C.f.a.s. CK-MB	11447394216	761333600720AE

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
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NB Ident. No.: 0123

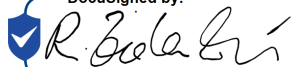
to which this declaration relates fulfils the requirements of Regulation EU 2017/746 on in-vitro diagnostic medical devices.

Mannheim, 14 April 2021

Roche Diagnostics GmbH

ppa./on behalf of the company

i.V./on behalf of the company

DocuSigned by:

0AFDA3CC08B94C8...

Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions

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Dr. Joachim Hoch
Director Global Regulatory Affairs
Centralised and Point of Care Solutions

Contact address:

Roche Diagnostics GmbH
Abt./Dept. Global Regulatory Affairs
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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: 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
C.f.a.s Proteins	11355279160	761333600715AM
C.f.a.s Proteins	11355279216	761333600716AP

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, 17 May 2021

Roche Diagnostics GmbH


ppa./on behalf of the company

i.V./on behalf of the company

DocuSigned by:

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Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions

DocuSigned by:

Joachim Hoch
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Dr. Joachim Hoch
Director Global Regulatory Affairs
Centralised and Point of Care Solutions

Contact address:

Roche Diagnostics GmbH
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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

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
Calibrator for automated systems	10759350190	761333600704AG
Calibrator for automated systems	10759350360	761333600705AJ

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
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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, 2 June 2021

Roche Diagnostics GmbH

ppa./on behalf of the company

i.V./on behalf of the company

DocuSigned by:

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Ralf Zielenski
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DocuSigned by:

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Dr. Joachim Hoch
Director Global Regulatory Affairs
Centralised and Point of Care Solutions

Contact address:

Roche Diagnostics GmbH
Abt./Dept. Global Regulatory Affairs
Sandhofer Strasse 116
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
CHOL2	03039773190	7613336002049P
CHOL2	04718917190	7613336003039S
CHOL2	05168538190	76133360000299
CHOL2	08057443190	761333600514A9
CHOL2	05168538214	761333600717AR

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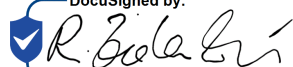
to which this declaration relates fulfils the requirements of Regulation EU 2017/746 on in-vitro diagnostic medical devices.

Mannheim, 14 April 2021

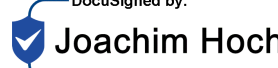
Roche Diagnostics GmbH

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Ralf Zielenski
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Centralised and Point of Care Solutions

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