

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
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: ☒ 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

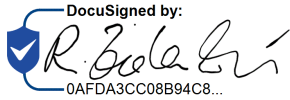
to which this declaration relates fulfils the requirements of Regulation EU 2017/746 on in-vitro diagnostic medical devices.

Mannheim, 20 April 2021

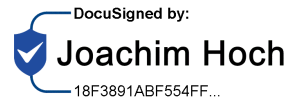
Roche Diagnostics GmbH

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

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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

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

Product Name	Cat. No.	Basic UDI-DI
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:

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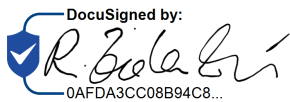
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Mannheim, 23 April 2021

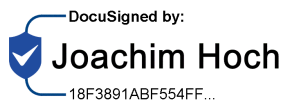
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Product Name	Cat. No.	Basic UDI-DI
CA2	05061482190	7613336003139V
CA2	05061504190	7613336003149X
CA2	05168449190	7613336003329Z
CA2	05168449214	761333600333A3
CA2	08057427190	761333600512A5

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

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Mannheim, 12 May 2021

Roche Diagnostics GmbH

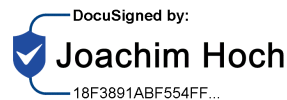
ppa./on behalf of the company

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Director Global Regulatory Affairs
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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
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NB Ident. No.: 0123

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Mannheim, 17 May 2021

Roche Diagnostics GmbH

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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
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
- ☐ 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

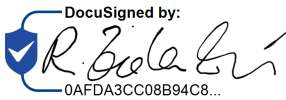
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Mannheim, 14 April 2021

Roche Diagnostics GmbH

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i.V./on behalf of the company

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Director Global Regulatory Affairs
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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
CK	05168546190	7613336000039B
CK	07190794190	761333600434AA
CK	07442017190	761333600458AQ
CK	08057460190	761333600515AB
CK	05168546214	7613336000059F

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:

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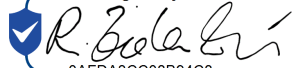
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Mannheim, 23 March 2021

Roche Diagnostics GmbH

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i.V./on behalf of the company

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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
RF Control Set	03005496122	7613336001049J
RF-II	05480167190	7613336001019C
RF-II	08058628190	7613336000149G
Preciset RF	12172828322	761333600147A4
RF-II	20764574322	761333600158A9

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):

Other: ☐ Common Specifications:

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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, 27 July 2021

Roche Diagnostics GmbH

ppa./on behalf of the company

i.V./on behalf of the company

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 **Joachim Hoch**
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Dr. Joachim Hoch
Director Global Regulatory Affairs
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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
CREJ2	04810716190	7613336003059W
CREJ2	05401755190	761333600093A6
CREJ2	06407137190	761333600186AE
CREJ2	06407137214	761333600187AG
CREJ2	08057532190	761333600520A4

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

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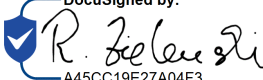
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Mannheim, 20 May 2021

Roche Diagnostics GmbH

ppa./on behalf of the company

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Product Name	Cat. No.	Basic UDI-DI
CRP4	07876033190	761333600633AJ
CRP4	07876424190	761333600634AL
CRP4	07876432190	761333600635AN
CRP4	08057591190	761333600639AW

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, 25 May 2021

Roche Diagnostics GmbH

ppa./on behalf of the company

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