

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
 80339 Munich
 Germany
NB Ident. No.: 0123

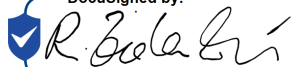
to which this declaration relates fulfils the requirements of Regulation EU 2017/746 on in-vitro diagnostic medical devices.

Mannheim, 14 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
Abt./Dept. Global Regulatory Affairs
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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
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Certificates:

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Mannheim, 17 May 2021

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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
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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:

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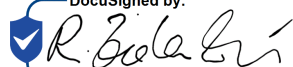
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Mannheim, 14 April 2021

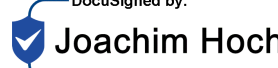
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Risk Class: A B C D

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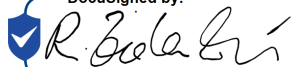
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Mannheim, 14 April 2021

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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
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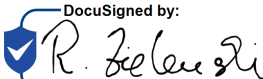
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Mannheim, 20 May 2021

Roche Diagnostics GmbH

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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
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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

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