

## **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

<b>Product Name</b>	<b>Cat. No.</b>	<b>Basic UDI-DI</b>
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

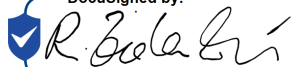
*to which this declaration relates fulfils the requirements of Regulation EU 2017/746 on in-vitro diagnostic medical devices.*

Mannheim, 14 April 2021

Roche Diagnostics GmbH

*ppa./on behalf of the company*

*i.V./on behalf of the company*

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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  
Sandhofer Strasse 116  
D-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

<b>Product Name</b>	<b>Cat. No.</b>	<b>Basic UDI-DI</b>
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

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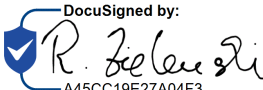
*to which this declaration relates fulfils the requirements of Regulation EU 2017/746 on in-vitro diagnostic medical devices.*

Mannheim, 20 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  
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**Address:** Sandhofer Strasse 116  
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 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
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
- 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, 25 May 2021

Roche Diagnostics GmbH

*ppa./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  
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D-68305 Mannheim

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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

<b>Product Name</b>	<b>Cat. No.</b>	<b>Basic UDI-DI</b>
ECO-D	05422485190	761333601366AR
ECO-D	05907543190	761333601389B5
ECO-D	05907543214	761333601390AN
ECO-D	06544410190	761333601435AK
ECO-D	08063354190	761333601533AL

**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, 31 August 2021


Roche Diagnostics GmbH

ppa./on behalf of the company

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Head Q&R Compliance, PRRC RDG  
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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
FERR4	04885317190	7613336003109P
FERR4	05172390190	7613336000609P
FERR4	08057648190	761333600523AA

**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, 25 May 2021

Roche Diagnostics GmbH

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i.V./on behalf of the company

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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  
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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

<b>Product Name</b>	<b>Cat. No.</b>	<b>Basic UDI-DI</b>
GLUC3	04404483190	761333600263A7
GLUC3	05168791190	7613336000279R
GLUC3	05168791214	761333600719AV
GLUC3	08057800190	761333600526AG

**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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 **Ralf Zielenski**  
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Ralf Zielenski  
Head of Quality  
Centralised and Point of Care Solutions

*i.V./on behalf of the company*

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 **Joachim Hoch**  
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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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**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

<b>Product Name</b>	<b>Cat. No.</b>	<b>Basic UDI-DI</b>
ISE Diluent Gen.2	04522630190	761333601279AV
ISE Diluent Gen.2	04880480190	761333601333AA

**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, 12 October 2021

Roche Diagnostics GmbH

*ppa./on behalf of the company*

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

*i.V./on behalf of the company*

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:** DE-MF-000006260

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

<b>Product Name</b>	<b>Cat. No.</b>	<b>Basic UDI-DI</b>
ISE Internal Standard Gen.2	04522320190	761333600651AL
ISE Internal Standard Gen.2	04880455190	761333600663AT
ISE Reference Electrolyte	10820652216	761333600706AL
ISE Reference Electrolyte	11360981216	761333600718AT
ISE Reference Electrolyte	08392013190	761333600687B9
ISE Standard High	11183982216	761333600711AD
ISE Standard Low	11183974216	761333600709AS

**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, 5 November 2021

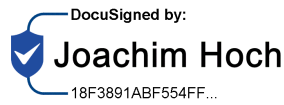
Roche Diagnostics GmbH

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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

<b>Product Name</b>	<b>Cat. No.</b>	<b>Basic UDI-DI</b>
LDHI2	03004732122	7613336001039G
LDHI2	05169330190	7613336000369S
LDHI2	05401674190	761333600089AF
LDHI2	08057958190	761333600532AB
LDHI2	05169330214	761333600722AJ

**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, 7 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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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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**Single Registration Number:** DE-MF-000006260

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

<b>Product Name</b>	<b>Cat. No.</b>	<b>Basic UDI-DI</b>
NaCl	04489357190	761333601272AF
NaCl Diluent 9%	20756350322	761333601659BB
NACL	08063494190	761333601536AS
NACL	05172152214	761333601358AS
NACL	05172152190	761333601357AQ
NaCl Diluent 9%	04774230190	761333601318AE

**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, 7 September 2021

Roche Diagnostics GmbH

ppa./on behalf of the company

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

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

<b>Product Name</b>	<b>Cat. No.</b>	<b>Basic UDI-DI</b>
Cell Wash Solution I/NaOH-D	04880285190	761333601329AK
Cell Wash Solution I/NaOH-D	07531869190	761333601496B7
Basic Wash	08302545190	761333601544AR

**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.: N/A*
- 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, 20 August 2021


Roche Diagnostics GmbH

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Ralf Zielenski  
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<b>Product Name</b>	<b>Cat. No.</b>	<b>Basic UDI-DI</b>
NaOHD	04489241190	761333601271AD
NaOHD	05172128190	761333601353AG
NaOHD	05172128214	761333601354AJ
NaOHD	08063451190	761333601534AN

**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  
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 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, 27 August 2021

Roche Diagnostics GmbH

*ppa./on behalf of the company*

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