DocuSign Envelope ID: 1EF4D976-6854-4CFA-B3DB-7953A0397940

# *EC Declaration of Conformity*

*as per Annex IV of the Regulation EU 2017/746 on in-vitro diagnostic medical devices*

*Manufacturer*:
*Address:*

Roche Diagnostics GmbH
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** |
|---|---|---|
| CKMB | 05168562190 | 7613336000069H |
| CKMB | 05168562214 | 761333602385B4 |
| 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)*
☐ *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*

Digitally signed by Lazari Cristina
Date: 2023.01.05 10:42:18 EET
Reason: MoldSign Signature
Location: Moldova

DocuSign Envelope ID: 1EF4D976-6854-4CFA-B3DB-7953A0397940

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

Mannheim, 25 August 2022

Roche Diagnostics GmbH

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

DocuSigned by:
Christina Schmid
59311CC1CDA8480...

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

ppa./*on behalf of the company*

DocuSigned by:
Stefan Scheib
FC5EDEC1054B44C...

Dr. Stefan Scheib
Network Lead Core Lab, Global Regulatory Affairs RDG

*Contact address*:

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

DocuSign Envelope ID: 223EA752-D527-4C77-9C6F-1BABB88D2880

# *EC Declaration of Conformity*

*as per Annex IV of the Regulation EU 2017/746 on in-vitro diagnostic medical devices*

*Manufacturer*:
*Address:*

Roche Diagnostics GmbH
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** |
|---|---|---|
| A1C-3 | 05336163190 | 7613336000739Y |
| A1C-3 | 05336180190 | 761333600075A4 |
| A1CX3 | 07559674190 | 761333600479AY |
| A1CX3 | 08056668190 | 7613336005009W |
| A1CX3 | 08445699190 | 7613336001189V |
| PreciControl HbA1c norm | 05479207190 | 761333600099AJ |
| PreciControl HbA1c norm | 05991323922 | 761333600172A3 |
| PreciControl HbA1c path | 05912504190 | 761333600375AK |
| PreciControl HbA1c path | 05991331922 | 761333600173A5 |
| C.f.a.s. HbA1c | 04528417190 | 761333600282AB |

*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*



Roche Diagnostics GmbH; Sandhofer Strasse 116; D-68305 Mannheim; Telefon +49-621-759-0; Telefax +49-621-759-2890

Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 3962 - Geschäftsführung: Claus Haberda; Andreas Schmitz - Aufsichtsratsvorsitzender: Dr. Thomas Schinecker

DocuSign Envelope ID: 223EA752-D527-4C77-9C6F-1BABB88D2880

| | |
|---|---|
| *NB Address:* | *Ridlerstraße 65*<br>*80339 Munich*<br>*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, 9 June 2021

Roche Diagnostics GmbH

ppa./*on behalf of the company*

DocuSigned by:
Ralf Zielenski
A45CC19E27A04F3...

Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions

ppa./*on behalf of the company*

DocuSigned by:
Joachim Hoch
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

DocuSign Envelope ID: 5A251676-330A-4978-8D70-0DF4C95D3A94

# *EC Declaration of Conformity*

*as per Annex IV of the Regulation EU 2017/746 on in-vitro diagnostic medical devices*

*Manufacturer*:
*Address:*

Roche Diagnostics GmbH
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** |
|---|---|---|
| A1CD | 07224648190 | 761333601476AZ |
| A1CD | 08463107190 | 761333601565AZ |
| A1CD2 | 05007232190 | 761333601344AF |
| A1CD2 | 04528182190 | 761333600652AN |
| Hemolyzing Reagent | 11488457122 | 761333601602AE |
| Hemolyzing Reagent Gen.2 | 04528328190 | 761333600653AQ |

*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*



Roche Diagnostics GmbH; Sandhofer Strasse 116; D-68305 Mannheim; Telefon +49-621-759-0; Telefax +49-621-759-2890

Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 3962 - Geschäftsführung: Claus Haberda; Andreas Schmitz - Aufsichtsratsvorsitzender: Dr. Thomas Schinecker

DocuSign Envelope ID: 5A251676-330A-4978-8D70-0DF4C95D3A94

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

Mannheim, 9 February 2022

Roche Diagnostics GmbH

ppa./*on behalf of the company*

DocuSigned by:
Ralf Zielenski
A7F0BA9FE91A46A...

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

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

DocuSigned by:
Dr. Joachim Hoch
18F3891ABF554FF...

Dr. Joachim Hoch
Clinical Chemistry SubChapter Lead,
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

DocuSign Envelope ID: 025F0581-067E-46B9-988A-CC3AA0EEE447

# *zwEC 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<br>68305 Mannheim<br>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*<br>*80339 Munich*<br>*Germany* |
| *NB Ident. No.:* | *0123* |



Roche Diagnostics GmbH; Sandhofer Strasse 116; D-68305 Mannheim; Telefon +49-621-759-0; Telefax +49-621-759-2890

Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 3962 - Geschäftsführung: Claus Haberda; Andreas Schmitz - Aufsichtsratsvorsitzender: Dr. Thomas Schinecker

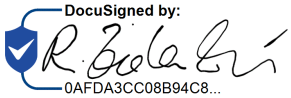
DocuSign Envelope ID: 025F0581-067E-46B9-988A-CC3AA0EEE447

*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*




Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions

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


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

DocuSign Envelope ID: E694EF1F-2DAA-44B3-B3E7-778B1CA5A425

# *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<br>68305 Mannheim<br>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** |
|---|---|---|
| ALBT2 | 04469658190 | 761333600267AF |
| ALBT2 | 05167043190 | 761333600328AA |
| ALBT2 | 05401500190 | 761333600086A9 |
| ALBT2 | 08056722190 | 761333600504A6 |

*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*<br>*80339 Munich*<br>*Germany* |
| *NB Ident. No.:* | *0123* |



Roche Diagnostics GmbH; Sandhofer Strasse 116; D-68305 Mannheim; Telefon +49-621-759-0; Telefax +49-621-759-2890

Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 3962 - Geschäftsführung: Claus Haberda; Andreas Schmitz - Aufsichtsratsvorsitzender: Dr. Thomas Schinecker

DocuSign Envelope ID: E694EF1F-2DAA-44B3-B3E7-778B1CA5A425

*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*

DocuSigned by:
Ralf Zielenski
A45CC19E27A04F3...

Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions

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

DocuSigned by:
Joachim Hoch
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

DocuSign Envelope ID: 854B7061-DE31-42A2-925A-AE5FAB02A45A

# *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<br>68305 Mannheim<br>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* |
| *NB Address:* | *Ridlerstraße 65*<br>*80339 Munich*<br>*Germany* |
| *NB Ident. No.:* | *0123* |



Roche Diagnostics GmbH; Sandhofer Strasse 116; D-68305 Mannheim; Telefon +49-621-759-0; Telefax +49-621-759-2890

Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 3962 - Geschäftsführung: Claus Haberda; Andreas Schmitz - Aufsichtsratsvorsitzender: Dr. Thomas Schinecker

DocuSign Envelope ID: 854B7061-DE31-42A2-925A-AE5FAB02A45A

*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*

DocuSigned by:
0AFDA3CC08B94C8...

Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions

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

DocuSigned by:
Joachim Hoch
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

DocuSign Envelope ID: 025F0581-067E-46B9-988A-CC3AA0EEE447

# *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<br>68305 Mannheim<br>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** |
|---|---|---|
| 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* |
| *NB Address:* | *Ridlerstraße 65*<br>*80339 Munich*<br>*Germany* |
| *NB Ident. No.:* | *0123* |



Roche Diagnostics GmbH; Sandhofer Strasse 116; D-68305 Mannheim; Telefon +49-621-759-0; Telefax +49-621-759-2890

Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 3962 - Geschäftsführung: Claus Haberda; Andreas Schmitz - Aufsichtsratsvorsitzender: Dr. Thomas Schinecker

DocuSign Envelope ID: 025F0581-067E-46B9-988A-CC3AA0EEE447

*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*

DocuSigned by:
0AFDA3CC08B94C8...

Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions

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

DocuSigned by:
Joachim Hoch
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

DocuSign Envelope ID: E694EF1F-2DAA-44B3-B3E7-778B1CA5A425

# *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<br>68305 Mannheim<br>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*<br>*80339 Munich*<br>*Germany* |
| *NB Ident. No.:* | *0123* |



Roche Diagnostics GmbH; Sandhofer Strasse 116; D-68305 Mannheim; Telefon +49-621-759-0; Telefax +49-621-759-2890

Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 3962 - Geschäftsführung: Claus Haberda; Andreas Schmitz - Aufsichtsratsvorsitzender: Dr. Thomas Schinecker

DocuSign Envelope ID: E694EF1F-2DAA-44B3-B3E7-778B1CA5A425

*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*

DocuSigned by:
Ralf Zielenski
A45CC19E27A04F3...

Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions

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

DocuSigned by:
Joachim Hoch
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

DocuSign Envelope ID: 28DDC97A-82DC-4909-84ED-95EDFEE99FAD

# *EC Declaration of Conformity*

*as per Annex IV of the Regulation EU 2017/746 on in-vitro diagnostic medical devices*

| | |
|---|---|
| *Manufacturer*:<br>*Address:* | Roche Diagnostics GmbH<br>Sandhofer Strasse 116<br>68305 Mannheim<br>Germany |
| *Single Registration Number:* | *TBD (application filed; confirmation pending)* |
| *Authorized Representative:*<br>*Address:* | N/A |
| *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** |
|---|---|---|
| ASLOT | 04489403190 | 761333600268AH |
| ASLOT | 05219191190 | 7613336000639V |
| ASLOT | 08105472190 | 7613336000529Q |

*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*<br>*80339 Munich*<br>*Germany* |
| *NB Ident. No.:* | *0123* |



Roche Diagnostics GmbH; Sandhofer Strasse 116; D-68305 Mannheim; Telefon +49-621-759-0; Telefax +49-621-759-2890

Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 3962 - Geschäftsführung: Claus Haberda; Andreas Schmitz - Aufsichtsratsvorsitzender: Dr. Thomas Schinecker

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

Mannheim, 6 April 2021

Roche Diagnostics GmbH

ppa./*on behalf of the company*

DocuSigned by:
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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
18F3891ABF554FF...

Dr. Joachim Hoch
Director Global Regulatory Affairs
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D-68305 Mannheim

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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*:<br>*Address:* | Roche Diagnostics GmbH<br>Sandhofer Strasse 116<br>68305 Mannheim<br>Germany |
| *Single Registration Number:* | *TBD (application filed; confirmation pending)* |
| *Authorized Representative:*<br>*Address:* | N/A |
| *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:*<br>*NB Address:* | *TÜV Süd Product Service GmbH*<br>*Ridlerstraße 65*<br>*80339 Munich*<br>*Germany* |
| *NB Ident. No.:* | *0123* |



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Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 3962 - Geschäftsführung: Claus Haberda; Andreas Schmitz - Aufsichtsratsvorsitzender: Dr. Thomas Schinecker

DocuSign Envelope ID: C7442A6B-F4FE-42F3-B7A5-BAA9A52D6CD4

*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*

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