

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
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

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, 9 June 2021

Roche Diagnostics GmbH

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