Docusign Envelope ID: CD2B3BB7-8F96-487B-AF8A-0927FEEBBF96

EU 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

Product Name	Cat. No.	Basic UDI-DI
AMIK2	05841224190	761333600354AB
AMIK2	08105383190	7613336000479X
AMIK2	04791959190	7613336003049U

Intended Use:

In vitro test for the quantitative determination of amikacin in serum and plasma on cobas c systems.

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.: V13 010283 0732

☐ 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 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, 03 March 2026

Roche Diagnostics GmbH

ppa./on behalf of the company

Signed by:
Nicole Zein

Dr. Nicole Zein
Site Quality Head / Network Lead, Mannheim

Mannheim, 28. Februar 2026

Roche Diagnostics GmbH

ppa./on behalf of the company

Signed by:
Stefan Scheib

Dr. Stefan Scheib
Global Head of Regulatory Affairs, Core Lab

Contact address:

Roche Diagnostics GmbH
Global Regulatory Affairs

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