

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
AMYL2	03183742122	7613336002089X

Intended Use:

In vitro test for the quantitative determination of α -amylase in human serum, plasma and urine on cobas c and COBAS INTEGRA systems.

Product Name	Cat. No.	Basic UDI-DI
AMYL2	05167027190	761333600325A4
AMYL2	05167027214	761333600326A6
AMYL2	08056811190	761333600507AC
AMYL2	08056811214	761333602604AR

Intended Use:

In vitro test for the quantitative determination of α -amylase in human serum, plasma and urine on cobas c systems.

Product Name	Cat. No.	Basic UDI-DI
AMYL2	05401496190	761333600085A7

Intended Use:

In vitro test for the quantitative determination of α -amylase in human serum, plasma and urine on the cobas c 111 system.

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

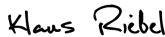
NB Ident. No.: 0123

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

Mannheim, 6 December 2024

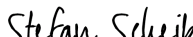
Roche Diagnostics GmbH

i.V./on behalf of the company

DocuSigned by:

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Dr. Klaus Riebel
Network Lead Site Head Penzberg & Cape Town

ppa./on behalf of the company

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

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