

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
CHOL2	05168538190	76133360000299
CHOL2	08057443190	761333600514A9
CHOL2	05168538214	761333600717AR
CHOL2	08057443214	761333602657BE

Intended Use:

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

Product Name	Cat. No.	Basic UDI-DI
CHOL2	03039773190	7613336002049P

Intended Use:

In vitro test for the quantitative determination of cholesterol in human serum and plasma on cobas c and COBAS INTEGRA systems.

Product Name	Cat. No.	Basic UDI-DI
CHOL2	04718917190	7613336003039S

Intended Use:

In vitro test for the quantitative determination of cholesterol in human serum and plasma 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

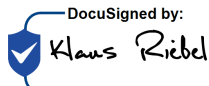
to which this declaration relates fulfils the requirements of Regulation EU 2017/746 on in-vitro diagnostic medical devices.

Mannheim, 10 October 2024

Roche Diagnostics GmbH

i.V./on behalf of the company

ppa./on behalf of the company

DocuSigned by:

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