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
cobas Lipid Panel Gen. 2	09200495190	761333602575BB

Intended Use:
The cobas Lipid Panel Gen. 2 assay is an in vitro diagnostic test designed to quantitatively determine total cholesterol (TC), high-density lipoprotein (HDL) cholesterol, and triglycerides (TG) in human capillary and K2/K3-EDTA-anticoagulated venous whole blood by photometric transmission measurement. A calculated value for low-density lipoprotein (LDL), non-HDL, and a TC/HDL ratio is provided.
The cobas Lipid Panel Gen. 2 assay is used for the diagnosis of dyslipidemias, as an aid in identifying patients who are at risk for developing atherosclerosis (the major cause of coronary artery disease), and for monitoring patients under cholesterol reduction therapy.
The cobas Lipid Panel Gen. 2 assay is intended for near-patient testing. The cobas Lipid Panel Gen. 2 assay is intended to be used with the cobas b 101 instrument and with the cobas click instrument.

Product Name	Cat. No.	Basic UDI-DI
cobas Lipid Control Gen. 2	09355545190	761333602570AZ

Intended Use:
cobas Lipid Control Gen. 2 is used for performing quality control of total cholesterol (TC), high-density lipoprotein (HDL) cholesterol, and triglycerides (TG) measurements with the cobas Lipid Panel Gen. 2 assay on the cobas b 101 instrument and the cobas click instrument.
cobas Lipid Control Gen. 2 is intended for near-patient testing.

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

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

	☐ 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.: *V10 010283 0641*
	☒ EU Technical Documentation Assessment Certificate No. (Class D, Near-Patient Testing, Self-Testing and Companion Diagnostics): *V74 010283 0726*
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 fulfills the requirements of Regulation EU 2017/746 on in-vitro diagnostic medical devices.

Mannheim, 12 May 2025

Roche Diagnostics GmbH

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

DocuSigned by:
Klaus Riebel
5E57330EEFE04C4...

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

Mannheim, 09. Mai 2025

Roche Diagnostics GmbH

ppa./*on behalf of the company*

DocuSigned by:
Stefan Scheib
FC5EDEC1054B44C...

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

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