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 HbA1c Test Gen. 2	09200509190	761333602574B9

Intended Use:
The cobas HbA1c Test Gen. 2 assay is an in vitro diagnostic test designed to quantitatively determine the % hemoglobin A1c (DCCT/NGSP) and mmol/mol hemoglobin A1c (IFCC) in human capillary and K2/K3-EDTA-anticoagulated venous whole blood by photometric transmission measurement. An estimated average glucose level (eAG) is calculated. HbA1c determinations are useful for monitoring of long-term blood glucose control in individuals with diabetes mellitus. Moreover, this test is to be used as an aid in diagnosis of diabetes and as an aid in identifying patients with prediabetes, who are at risk for developing diabetes.
The cobas HbA1c Test Gen. 2 assay is intended for near-patient testing.
The cobas HbA1c Test 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 HbA1c Control Gen. 2	09355537190	761333602569BG

Intended Use:
cobas HbA1c Control Gen. 2 is used for performing quality control of HbA1c measurements with the cobas HbA1c Test Gen. 2 assay on the cobas b 101 instrument and the cobas click instrument.
cobas HbA1c 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

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

Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 3962 - Geschäftsführung: Dr. Claudia Fleischer; Dr. Virginia Bastian
Aufsichtsratsvorsitzender: Dr. Thomas Schinecker

	☐ 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.: *V10 010283 0641*
	☒ EU Technical Documentation Assessment Certificate No. (Class D, Near-Patient Testing, Self-Testing and Companion Diagnostics): *V76 010283 0727*
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, 30 June 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, 27. Juni 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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