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 CRP Test Gen. 2	09200487190	761333602576BD

Intended Use:
The cobas CRP Test Gen. 2 assay is an in vitro diagnostic test designed to quantitatively determine the C-reactive protein (CRP) in human capillary whole blood and serum, K2/K3-EDTA- and lithium-heparin-anticoagulated venous whole blood and plasma by photometric transmission measurement. Measurement of CRP is of use for the evaluation of inflammatory disorders and associated diseases, infection and tissue injury.
The cobas CRP Test Gen. 2 assay is intended for near-patient testing.
The cobas CRP 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 CRP Control Gen. 2	09355553190	761333602571B3

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

☐ Technical Documentation Assessment Class B/C/D for Self-Testing – 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 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 0722*
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, 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

Contact address: Roche Diagnostics GmbH
Abt./Dept. Global Regulatory Affairs
Sandhofer Strasse 116
D-68305 Mannheim