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. / REF	Basic UDI-DI
Roche CARDIAC D-Dimer	04877802190	761333601328AH
Roche CARDIAC D-Dimer	04877802191	7613336020209R

Intended Use:

The Roche CARDIAC D-Dimer is an in vitro diagnostic quantitative immunological test for the detection of d-dimer in heparinized venous blood for use with the cobas h 232 instrument.
The Roche CARDIAC D-Dimer test serves as an aid in diagnosis when deep venous thrombosis and pulmonary embolism is suspected. A negative d-dimer result is an indication that these diseases can be ruled out with high probability.
The Roche CARDIAC D-Dimer test is intended for near-patient testing.
Not for self-testing.

Product Name	Cat. No. / REF	Basic UDI-DI
Roche CARDIAC Control D-Dimer	04890523190	761333601339AN

Intended Use:

The Roche CARDIAC Control D-Dimer is used with the Roche CARDIAC D-Dimer test for quality control testing on the cobas h 232 instrument.
The Roche CARDIAC Control D-Dimer is intended for near-patient testing.
Not for self-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
☒ 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.: V13 010283 0733
	☒ EU Technical Documentation Assessment Certificate No. (Class D, Near-Patient Testing, Self-Testing and Companion Diagnostics): V74 010283 0688
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 March 2026

Roche Diagnostics GmbH

ppa./on behalf of the company

Signed by:
Nicole Zein

Dr. Nicole Zein
Site Quality Head / Network Lead, Mannheim

Mannheim, 10. März 2026

Roche Diagnostics GmbH

ppa./on behalf of the company

Signed by:
Stefan Scheib

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

Contact address:

Roche Diagnostics GmbH
Global Regulatory Affairs

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