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**
CoaguChek PT Test	06688721003	761333600818AY
CoaguChek PT Test	06688721016	761333600820AK
CoaguChek PT Test	06688721019	761333600821AM
CoaguChek PT Test	06688721070	761333600822AP
CoaguChek PT Test	06688721170	761333600823AR
CoaguChek PT Test	06688721045	761333602098AW

Intended Use:
The CoaguChek PT Test is an in-vitro assay for the determination of prothrombin time (PT) using the CoaguChek Pro II meter. It is an aid for the detection of factor deficiencies and for monitoring of vitamin K antagonist therapy. The test can be used with either capillary, venous, or arterial fresh whole blood.
The CoaguChek PT Test 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.: V10 010283 0641*
☒ *EU Technical Documentation Assessment Certificate No. (Class D, Near-Patient Testing, Self-Testing and Companion Diagnostics): V74 010283 0642*

Other: ☐ *Common Specifications:*

Notified Body (NB) Name: *TÜV Süd Product Service GmbH*

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: Claus Haberda; Clemens Schmid - Aufsichtsratsvorsitzender: Dr. Thomas Schinecker

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, 15 November 2022

Roche Diagnostics GmbH

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

DocuSigned by:
Bernd Roettinger
00ABEBB0E89341C...

Dr. Bernd Röttinger
Head of Pre-Market Quality Point of Care

ppa./*on behalf of the company*

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