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 XS PT Test	04625315003	761333601282AJ
CoaguChek XS PT Test	04625315016	761333601283AL
CoaguChek XS PT Test	04625315019	761333601284AN
CoaguChek XS PT Test	04625315045	7613336020239X
CoaguChek XS PT Test	04625315070	761333601285AQ
CoaguChek XS PT Test	04625315133	7613336020249Z
CoaguChek XS PT Test	04625315172	761333601286AS
CoaguChek XS PT Test	04625358003	761333601287AU
CoaguChek XS PT Test	04625358016	761333601288AW
CoaguChek XS PT Test	04625358019	761333601289AY
CoaguChek XS PT Test	04625358045	761333602025A3
CoaguChek XS PT Test	04625358070	761333601290AH
CoaguChek XS PT Test	04625358170	761333601291AK
CoaguChek XS PT Test	04625358172	761333601292AM
CoaguChek XS PT Test	04625358243	761333602026A5
CoaguChek XS PT Test	04625374190	761333601293AP

Intended Use:
The CoaguChek XS PT Test is an in-vitro assay for the determination of prothrombin time (PT) in capillary or venous fresh whole blood using the CoaguChek XS/XS Plus/XS Pro meters. It can be used for monitoring of vitamin K antagonist therapy.
The CoaguChek XS PT Test is intended for near-patient testing as well as 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*

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

	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 0654*
Other:	☐ *Common Specifications:*
Notified Body (NB) Name: *NB Address:*	*TÜV Süd Product Service GmbH* *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, 16 December 2022

Roche Diagnostics GmbH

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

DocuSigned by:
Christina Schmid
59311CC1CDA8480...

Dr. Christina Schmid
Head of Pre-Market Quality Core Lab

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