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, under the sole responsibility, declares that the product/the product line

Product Name	Cat. No.	Basic UDI-DI
CoaguChek INRange	07404379003	761333601486B4
CoaguChek INRange	07404379015	761333601487B6
CoaguChek INRange	07404379016	761333601488B8
CoaguChek INRange	07404379019	761333601490AT
CoaguChek INRange	07404379037	761333601491AV
CoaguChek INRange	07404379170	761333601492AX
CoaguChek INRange	07404379018	761333601489BA
CoaguChek INRange	07404379191	7613336021139Z
CoaguChek INRange	07404379133	7613336021129X

Intended Use:

The CoaguChek® INRange system, consisting of the CoaguChek INRange meter and the CoaguChek XS® PT Test PST test strip, is intended for the determination of prothrombin time (PT) in fresh capillary blood. It is intended for use by properly selected and appropriately trained patients and their respective caregivers. The prothrombin time (PT) test is a general coagulation test to monitor Vitamin K Antagonist therapy. The CoaguChek INRange system is intended for single patient self-testing only. It is not intended for use in a professional setting.

Risk Class: ☐ *A* ☐ *B* ☒ *C* ☐ *D*

Conformity Route:

☐ *Self-Declaration of Conformity (Class A)*
☐ *Technical Documentation Assessment Class B/C – 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*

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Sitz der Gesellschaft: Mannheim - Registergericht: AG Mannheim HRB 3962 - Geschäftsführung: Claus Haberda; Clemens Schmid - Aufsichtsratsvorsitzender: Dr. Thomas Schinecker

Certificates:	☒ *EU QM Certificate No.: V10 010283 0641* ☒ *EU Technical Documentation Assessment Certificate No. (Near-Patient Testing, Self-Testing and Companion Diagnostics): V74 010283 0643*
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

and

- *fulfills the requirements of DIRECTIVE 2011/65/EU of the European Parliament and of the Council of 8 June 2011 (RoHS) on the restriction of the use of certain hazardous substances in electrical and electronic equipment.*

and

- *fulfills the requirements of Directive 2014/53/EU of the European Parliament and Council of 16 April 2014 (RED) relating to the making available on the market of radio equipment.*

Mannheim, 3 November 2022

Roche Diagnostics GmbH

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

DocuSigned by:
Bernd Röttinger
00ABEBB0E89341C...

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

ppa./*on behalf of the company*

DocuSigned by:
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