ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-099

Product Service

EU Technical Documentation Assessment Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices,
Annex IX, Chapter II, Section 4, 5.1
(Class C and B Devices for self-testing and near patient testing)

No. V74 010283 0642 Rev. 01

Manufacturer: **Roche Diagnostics GmbH**
Sandhofer Strasse 116
68305 Mannheim
GERMANY

SRN Manufacturer: DE-MF-000006260

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has drawn up and presented a Technical Documentation according to Annex II and III of the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices. Details on devices covered by the Technical Documentation are described on the following page(s).
The Report referenced below summarizes the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX, Chapter II, Section 4, 5.1 of this regulation with a positive result.
In order to place the devices on the market with CE-marking, an EU Quality Management System Certificate pursuant to Annex IX Chapters I and III is necessary in addition to this EU Technical Documentation Assessment Certificate.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V74 010283 0642 Rev. 01

Report No.: 713231302-02

Preceding Certificate No.: V74 010283 0642 Rev. 00

Valid from: 2022-02-21
Valid until: 2026-09-23

Date of Initial Issuance: 2021-09-24

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-02-21

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No. V74 010283 0642 Rev. 01

Classification:	C
Device Group:	W0103020801 - PROTHROMBIN TIME RT & POC
Basic UDI-DI:	761333600818AY
Intended Purpose:	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.
Device(s):	CoaguChek PT Test Ref. No.: 06688721003

Classification:	C
Device Group:	W0103020801 - PROTHROMBIN TIME RT & POC
Basic UDI-DI:	761333600820AK
Intended Purpose:	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.
Device(s):	CoaguChek PT Test Ref. No.: 06688721016

Classification:	C
Device Group:	W0103020801 - PROTHROMBIN TIME RT & POC
Basic UDI-DI:	761333600821AM
Intended Purpose:	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.
Device(s):	CoaguChek PT Test Ref. No.: 06688721019

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No. V74 010283 0642 Rev. 01

Classification:	C
Device Group:	W0103020801 - PROTHROMBIN TIME RT & POC
Basic UDI-DI:	761333600822AP
Intended Purpose:	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.
Device(s):	CoaguChek PT Test Ref. No.: 06688721070

Classification:	C
Device Group:	W0103020801 - PROTHROMBIN TIME RT & POC
Basic UDI-DI:	761333600823AR
Intended Purpose:	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.
Device(s):	CoaguChek PT Test Ref. No.: 06688721170

Classification:	C
Device Group:	W0103020801 - PROTHROMBIN TIME RT & POC
Basic UDI-DI:	761333602098AW
Intended Purpose:	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.
Device(s):	CoaguChek PT Test Ref. No.: 06688721045

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No. V74 010283 0642 Rev. 01

Classification:	C
Device Group:	W010302080501 - HEMOSTASIS CONTROLS RT & POC
Basic UDI-DI:	761333600824AT
Intended Purpose:	CoaguChek PT Controls are used for system checks and quality control testing of prothrombin time with the CoaguChek Pro II meter and CoaguChek PT Test strips. The CoaguChek PT Controls are intended for near-patient testing. Not for self-testing.
Device(s):	CoaguChek PT Controls Ref. No.: 07682573003
Classification:	C
Device Group:	W010302080501 - HEMOSTASIS CONTROLS RT & POC
Basic UDI-DI:	761333600819B2
Intended Purpose:	CoaguChek PT Controls are used for system checks and quality control testing of prothrombin time with the CoaguChek Pro II meter and CoaguChek PT Test strips. The CoaguChek PT Controls are intended for near-patient testing. Not for self-testing.
Device(s):	CoaguChek PT Controls Ref. No.: 06679684190
The validity of this certificate depends on conditions and/or is limited to the following:	-none-

Revision History:

Rev.	Dated	Report
00	2021-09-24	713209686-01

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