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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 0654 Rev. 00

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 0654 Rev. 00

Report No.: 713224738

Valid from: 2022-07-25
Valid until: 2027-07-24

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-07-25

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No. V74 010283 0654 Rev. 00

Classification:	C
Device Group:	W0103020801 - PROTHROMBIN TIME RT & POC
Basic UDI-DI:	761333601282AJ
Intended Purpose:	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.
Device(s):	CoaguChek XS PT Test Ref. No. 04625315003

Classification:	C
Device Group:	W0103020801 - PROTHROMBIN TIME RT & POC
Basic UDI-DI:	761333601283AL
Intended Purpose:	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.
Device(s):	CoaguChek XS PT Test Ref. No. 04625315016

Classification:	C
Device Group:	W0103020801 - PROTHROMBIN TIME RT & POC
Basic UDI-DI:	761333601284AN
Intended Purpose:	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.
Device(s):	CoaguChek XS PT Test Ref. No. 04625315019

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No. V74 010283 0654 Rev. 00

Classification:	C
Device Group:	W0103020801 - PROTHROMBIN TIME RT & POC
Basic UDI-DI:	761333601285AQ
Intended Purpose:	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.
Device(s):	CoaguChek XS PT Test Ref. No. 04625315070

Classification:	C
Device Group:	W0103020801 - PROTHROMBIN TIME RT & POC
Basic UDI-DI:	7613336020239X
Intended Purpose:	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.
Device(s):	CoaguChek XS PT Test Ref. No. 04625315045

Classification:	C
Device Group:	W0103020801 - PROTHROMBIN TIME RT & POC
Basic UDI-DI:	7613336020249Z
Intended Purpose:	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.
Device(s):	CoaguChek XS PT Test Ref. No. 04625315133

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No. V74 010283 0654 Rev. 00

Classification:	C
Device Group:	W0103020801 - PROTHROMBIN TIME RT & POC
Basic UDI-DI:	761333601286AS
Intended Purpose:	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.
Device(s):	CoaguChek XS PT Test Ref. No. 04625315172

Classification:	C
Device Group:	W0103020801 - PROTHROMBIN TIME RT & POC
Basic UDI-DI:	761333601287AU
Intended Purpose:	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.
Device(s):	CoaguChek XS PT Test Ref. No. 04625358003

Classification:	C
Device Group:	W0103020801 - PROTHROMBIN TIME RT & POC
Basic UDI-DI:	761333601288AW
Intended Purpose:	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.
Device(s):	CoaguChek XS PT Test Ref. No. 04625358016

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Classification:	C
Device Group:	W0103020801 - PROTHROMBIN TIME RT & POC
Basic UDI-DI:	761333601289AY
Intended Purpose:	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.
Device(s):	CoaguChek XS PT Test Ref. No. 04625358019

Classification:	C
Device Group:	W0103020801 - PROTHROMBIN TIME RT & POC
Basic UDI-DI:	761333601290AH
Intended Purpose:	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.
Device(s):	CoaguChek XS PT Test Ref. No. 04625358070

Classification:	C
Device Group:	W0103020801 - PROTHROMBIN TIME RT & POC
Basic UDI-DI:	761333601291AK
Intended Purpose:	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.
Device(s):	CoaguChek XS PT Test Ref. No. 04625358170

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Classification:	C
Device Group:	W0103020801 - PROTHROMBIN TIME RT & POC
Basic UDI-DI:	761333601292AM
Intended Purpose:	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.
Device(s):	CoaguChek XS PT Test Ref. No. 04625358172

Classification:	C
Device Group:	W0103020801 - PROTHROMBIN TIME RT & POC
Basic UDI-DI:	761333602025A3
Intended Purpose:	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.
Device(s):	CoaguChek XS PT Test Ref. No. 04625358045

Classification:	C
Device Group:	W0103020801 - PROTHROMBIN TIME RT & POC
Basic UDI-DI:	761333602026A5
Intended Purpose:	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.
Device(s):	CoaguChek XS PT Test Ref. No. 04625358243

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Classification:	C
Device Group:	W0103020801 - PROTHROMBIN TIME RT & POC
Basic UDI-DI:	761333601293AP
Intended Purpose:	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.
Device(s):	CoaguChek XS PT Test Ref. No. 04625374190

Classification:	C
Device Group:	W010302080501 - HEMOSTASIS CONTROLS RT & POC
Basic UDI-DI:	7613336013039Z
Intended Purpose:	CoaguChek XS PT Controls are used for system checks and quality control testing of prothrombin time with the CoaguChek XS Plus or CoaguChek XS Pro meter and CoaguChek XS PT Test strips. The CoaguChek XS PT Controls are intended for near-patient testing. Not for self-testing.
Device(s):	CoaguChek XS PT Controls Ref. No. 04696522003

Classification:	C
Device Group:	W010302080501 - HEMOSTASIS CONTROLS RT & POC
Basic UDI-DI:	761333601304A3
Intended Purpose:	CoaguChek XS PT Controls are used for system checks and quality control testing of prothrombin time with the CoaguChek XS Plus or CoaguChek XS Pro meter and CoaguChek XS PT Test strips. The CoaguChek XS PT Controls are intended for near-patient testing. Not for self-testing.
Device(s):	CoaguChek XS PT Controls Ref. No. 04696522190

The validity of this certificate depends on conditions and/or is limited to the following:	-none-

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