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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 0662 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 0662 Rev. 00

Report No.: 713257675

Valid from: 2022-09-22
Valid until: 2027-09-21

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-09-22

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No. V74 010283 0662 Rev. 00

Classification:	B
Device Group:	W0101060204 - URINE MULTI-CONSTITUENT TEST STRIPS (MANUAL)
Basic UDI-DI:	761333601278AT
Intended Purpose:	The Combur-Tests are test strips for in vitro qualitative or semi quantitative determination of pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, erythrocytes and specific gravity in urine by visual reading. These measurements are useful in the evaluation of renal, urinary, hepatic and metabolic disorders. Combur-Tests are test strips for single use only. Combur-Tests are screening tests and can aid in the diagnosis of pathological conditions. The test is intended for near-patient testing. Not for self-testing.
Device(s):	04510089056
Device(s):	Combur10 Test
Classification:	B
Device Group:	W0101060204 - URINE MULTI-CONSTITUENT TEST STRIPS (MANUAL)
Basic UDI-DI:	761333601277AR
Intended Purpose:	The Combur-Tests are test strips for in vitro qualitative or semi quantitative determination of pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, erythrocytes and specific gravity in urine by visual reading. These measurements are useful in the evaluation of renal, urinary, hepatic and metabolic disorders. Combur-Tests are test strips for single use only. Combur-Tests are screening tests and can aid in the diagnosis of pathological conditions. The test is intended for near-patient testing. Not for self-testing.
Device(s):	04510062171
Device(s):	Combur10 Test

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No. V74 010283 0662 Rev. 00

Classification:	B
Device Group:	W0101060204 - URINE MULTI-CONSTITUENT TEST STRIPS (MANUAL)
Basic UDI-DI:	761333601275AM
Intended Purpose:	The Combur-Tests are test strips for in vitro qualitative or semi quantitative determination of pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, erythrocytes and specific gravity in urine by visual reading. These measurements are useful in the evaluation of renal, urinary, hepatic and metabolic disorders. Combur-Tests are test strips for single use only. Combur-Tests are screening tests and can aid in the diagnosis of pathological conditions. The test is intended for near-patient testing. Not for self-testing.
Device(s):	04510046040
Device(s):	Combur9 Test
Classification:	B
Device Group:	W0101060204 - URINE MULTI-CONSTITUENT TEST STRIPS (MANUAL)
Basic UDI-DI:	761333601276AP
Intended Purpose:	The Combur-Tests are test strips for in vitro qualitative or semi quantitative determination of pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, erythrocytes and specific gravity in urine by visual reading. These measurements are useful in the evaluation of renal, urinary, hepatic and metabolic disorders. Combur-Tests are test strips for single use only. Combur-Tests are screening tests and can aid in the diagnosis of pathological conditions. The test is intended for near-patient testing. Not for self-testing.
Device(s):	04510054056
Device(s):	Combur9 Test

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Classification:	B
Device Group:	W0101060204 - URINE MULTI-CONSTITUENT TEST STRIPS (MANUAL)
Basic UDI-DI:	761333601274AK
Intended Purpose:	The Combur-Tests are test strips for in vitro qualitative or semi quantitative determination of pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, erythrocytes and specific gravity in urine by visual reading. These measurements are useful in the evaluation of renal, urinary, hepatic and metabolic disorders. Combur-Tests are test strips for single use only. Combur-Tests are screening tests and can aid in the diagnosis of pathological conditions. The test is intended for near-patient testing. Not for self-testing.
Device(s):	04510038191
Device(s):	Combur9 Test
Classification:	B
Device Group:	W0101060204 - URINE MULTI-CONSTITUENT TEST STRIPS (MANUAL)
Basic UDI-DI:	761333601593B6
Intended Purpose:	The Combur-Tests are test strips for in vitro qualitative or semi quantitative determination of pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, erythrocytes and specific gravity in urine by visual reading. These measurements are useful in the evaluation of renal, urinary, hepatic and metabolic disorders. Combur-Tests are test strips for single use only. Combur-Tests are screening tests and can aid in the diagnosis of pathological conditions. The test is intended for near-patient testing. Not for self-testing.
Device(s):	11008552173
Device(s):	Combur7 Test

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Classification:	B
Device Group:	W0101060204 - URINE MULTI-CONSTITUENT TEST STRIPS (MANUAL)
Basic UDI-DI:	761333601594B8
Intended Purpose:	The Combur-Tests are test strips for in vitro qualitative or semi quantitative determination of pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, erythrocytes and specific gravity in urine by visual reading. These measurements are useful in the evaluation of renal, urinary, hepatic and metabolic disorders. Combur-Tests are test strips for single use only. Combur-Tests are screening tests and can aid in the diagnosis of pathological conditions. The test is intended for near-patient testing. Not for self-testing.
Device(s):	11008552191
Device(s):	Combur7 Test
Classification:	B
Device Group:	W0101060204 - URINE MULTI-CONSTITUENT TEST STRIPS (MANUAL)
Basic UDI-DI:	761333601679BH
Intended Purpose:	The Combur-Tests are test strips for in vitro qualitative or semi quantitative determination of pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, erythrocytes and specific gravity in urine by visual reading. These measurements are useful in the evaluation of renal, urinary, hepatic and metabolic disorders. Combur-Tests are test strips for single use only. Combur-Tests are screening tests and can aid in the diagnosis of pathological conditions. The test is intended for near-patient testing. Not for self-testing.
Device(s):	11008552170
Device(s):	Combur7 Test

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Classification:	B
Device Group:	W0101060204 - URINE MULTI-CONSTITUENT TEST STRIPS (MANUAL)
Basic UDI-DI:	761333601591B2
Intended Purpose:	The Combur-Tests are test strips for in vitro qualitative or semi quantitative determination of pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, erythrocytes and specific gravity in urine by visual reading. These measurements are useful in the evaluation of renal, urinary, hepatic and metabolic disorders. Combur-Tests are test strips for single use only. Combur-Tests are screening tests and can aid in the diagnosis of pathological conditions. The test is intended for near-patient testing. Not for self-testing.
Device(s):	11896962257
Device(s):	Combur6 Test
Classification:	B
Device Group:	W0101060204 - URINE MULTI-CONSTITUENT TEST STRIPS (MANUAL)
Basic UDI-DI:	761333601584B5
Intended Purpose:	The Combur-Tests are test strips for in vitro qualitative or semi quantitative determination of pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, erythrocytes and specific gravity in urine by visual reading. These measurements are useful in the evaluation of renal, urinary, hepatic and metabolic disorders. Combur-Tests are test strips for single use only. Combur-Tests are screening tests and can aid in the diagnosis of pathological conditions. The test is intended for near-patient testing. Not for self-testing.
Device(s):	11893467255
Device(s):	Combur5 Test

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Classification:	B
Device Group:	W0101060204 - URINE MULTI-CONSTITUENT TEST STRIPS (MANUAL)
Basic UDI-DI:	761333602018A6
Intended Purpose:	The Combur-Tests are test strips for in vitro qualitative or semi quantitative determination of pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, erythrocytes and specific gravity in urine by visual reading. These measurements are useful in the evaluation of renal, urinary, hepatic and metabolic disorders. Combur-Tests are test strips for single use only. Combur-Tests are screening tests and can aid in the diagnosis of pathological conditions. The test is intended for near-patient testing. Not for self-testing.
Device(s):	11893467170
Device(s):	Combur5 Test
Classification:	B
Device Group:	W0101060204 - URINE MULTI-CONSTITUENT TEST STRIPS (MANUAL)
Basic UDI-DI:	761333601587BB
Intended Purpose:	The Combur-Tests are test strips for in vitro qualitative or semi quantitative determination of pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, erythrocytes and specific gravity in urine by visual reading. These measurements are useful in the evaluation of renal, urinary, hepatic and metabolic disorders. Combur-Tests are test strips for single use only. Combur-Tests are screening tests and can aid in the diagnosis of pathological conditions. The test is intended for near-patient testing. Not for self-testing.
Device(s):	11896822191
Device(s):	Combur4 Test N

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Classification:	B
Device Group:	W0101060204 - URINE MULTI-CONSTITUENT TEST STRIPS (MANUAL)
Basic UDI-DI:	761333601585B7
Intended Purpose:	The Combur-Tests are test strips for in vitro qualitative or semi quantitative determination of pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, erythrocytes and specific gravity in urine by visual reading. These measurements are useful in the evaluation of renal, urinary, hepatic and metabolic disorders. Combur-Tests are test strips for single use only. Combur-Tests are screening tests and can aid in the diagnosis of pathological conditions. The test is intended for near-patient testing. Not for self-testing.
Device(s):	11896814056
Device(s):	Combur3 Test
Classification:	B
Device Group:	W0101060204 - URINE MULTI-CONSTITUENT TEST STRIPS (MANUAL)
Basic UDI-DI:	761333601586B9
Intended Purpose:	The Combur-Tests are test strips for in vitro qualitative or semi quantitative determination of pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, erythrocytes and specific gravity in urine by visual reading. These measurements are useful in the evaluation of renal, urinary, hepatic and metabolic disorders. Combur-Tests are test strips for single use only. Combur-Tests are screening tests and can aid in the diagnosis of pathological conditions. The test is intended for near-patient testing. Not for self-testing.
Device(s):	11896814191
Device(s):	Combur3 Test

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Classification:	B
Device Group:	W0101060204 - URINE MULTI-CONSTITUENT TEST STRIPS (MANUAL)
Basic UDI-DI:	761333602016A2
Intended Purpose:	The Combur-Tests are test strips for in vitro qualitative or semi quantitative determination of pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, erythrocytes and specific gravity in urine by visual reading. These measurements are useful in the evaluation of renal, urinary, hepatic and metabolic disorders. Combur-Tests are test strips for single use only. Combur-Tests are screening tests and can aid in the diagnosis of pathological conditions. The test is intended for near-patient testing. Not for self-testing.
Device(s):	11896814170
Device(s):	Combur3 Test
Classification:	B
Device Group:	W0101060204 - URINE MULTI-CONSTITUENT TEST STRIPS (MANUAL)
Basic UDI-DI:	761333601588BD
Intended Purpose:	The Combur-Tests are test strips for in vitro qualitative or semi quantitative determination of pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, erythrocytes and specific gravity in urine by visual reading. These measurements are useful in the evaluation of renal, urinary, hepatic and metabolic disorders. Combur-Tests are test strips for single use only. Combur-Tests are screening tests and can aid in the diagnosis of pathological conditions. The test is intended for near-patient testing. Not for self-testing.
Device(s):	11896857191
Device(s):	Combur3 Test E

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Classification:	B
Device Group:	W0101060204 - URINE MULTI-CONSTITUENT TEST STRIPS (MANUAL)
Basic UDI-DI:	761333602017A4
Intended Purpose:	The Combur-Tests are test strips for in vitro qualitative or semi quantitative determination of pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, erythrocytes and specific gravity in urine by visual reading. These measurements are useful in the evaluation of renal, urinary, hepatic and metabolic disorders. Combur-Tests are test strips for single use only. Combur-Tests are screening tests and can aid in the diagnosis of pathological conditions. The test is intended for near-patient testing. Not for self-testing.
Device(s):	11896857170
Device(s):	Combur3 Test E
Classification:	B
Device Group:	W0101060204 - URINE MULTI-CONSTITUENT TEST STRIPS (MANUAL)
Basic UDI-DI:	761333601589BF
Intended Purpose:	The Combur-Tests are test strips for in vitro qualitative or semi quantitative determination of pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, erythrocytes and specific gravity in urine by visual reading. These measurements are useful in the evaluation of renal, urinary, hepatic and metabolic disorders. Combur-Tests are test strips for single use only. Combur-Tests are screening tests and can aid in the diagnosis of pathological conditions. The test is intended for near-patient testing. Not for self-testing.
Device(s):	11896890191
Device(s):	Combur2 Test LN

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Classification:	B
Device Group:	W0101060204 - URINE MULTI-CONSTITUENT TEST STRIPS (MANUAL)
Basic UDI-DI:	7613336020159Y
Intended Purpose:	The Combur-Tests are test strips for in vitro qualitative or semi quantitative determination of pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, erythrocytes and specific gravity in urine by visual reading. These measurements are useful in the evaluation of renal, urinary, hepatic and metabolic disorders. Combur-Tests are test strips for single use only. Combur-Tests are screening tests and can aid in the diagnosis of pathological conditions. The test is intended for near-patient testing. Not for self-testing.
Device(s):	11896890170
Device(s):	Combur2 Test LN
The validity of this certificate depends on conditions and/or is limited to the following:	Not all individually listed device variants cover all test parameters specified in the respective intended use, as there is a common IFU for all devices

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