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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 0655 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 0655 Rev. 00

Report No.: 713233378

Valid from: 2022-07-22
Valid until: 2027-07-21

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-07-22

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No. V74 010283 0655 Rev. 00

Classification:	B
Device Group:	W0101060204 - URINE MULTI-CONSTITUENT TEST STRIPS (MANUAL) W0101060205 - URINE MULTI-CONSTITUENT TEST STRIPS (AUTOMATED)
Basic UDI-DI:	761333601673B5
Intended Purpose:	The Combur10 Test UX are test strips for the in vitro qualitative or semi-quantitative determination of pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, erythrocytes and specific gravity in urine with the Urisys 1100 urine analyzer and by visual reading. These measurements are useful in the evaluation of renal, urinary, hepatic and metabolic disorders. Combur10 Test UX are test strips for single use only. Combur10 Test UX are screening tests and can aid in the diagnosis of pathological conditions. Not for self-testing. The test is intended for near-patient testing.
Device(s):	Combur10 Test UX Cat. No. 11544373005

Classification:	B
Device Group:	W0101060204 - URINE MULTI-CONSTITUENT TEST STRIPS (MANUAL) W0101060205 - URINE MULTI-CONSTITUENT TEST STRIPS (AUTOMATED)
Basic UDI-DI:	761333601674B7
Intended Purpose:	The Combur10 Test UX are test strips for the in vitro qualitative or semi-quantitative determination of pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, erythrocytes and specific gravity in urine with the Urisys 1100 urine analyzer and by visual reading. These measurements are useful in the evaluation of renal, urinary, hepatic and metabolic disorders. Combur10 Test UX are test strips for single use only. Combur10 Test UX are screening tests and can aid in the diagnosis of pathological conditions. Not for self-testing. The test is intended for near-patient testing.
Device(s):	Combur10 Test UX Cat. No. 11544373053

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No. V74 010283 0655 Rev. 00

Classification:	B
Device Group:	W0101060204 - URINE MULTI-CONSTITUENT TEST STRIPS (MANUAL) W0101060205 - URINE MULTI-CONSTITUENT TEST STRIPS (AUTOMATED)
Basic UDI-DI:	761333601675B9
Intended Purpose:	The Combur10 Test UX are test strips for the in vitro qualitative or semi-quantitative determination of pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, erythrocytes and specific gravity in urine with the Urisys 1100 urine analyzer and by visual reading. These measurements are useful in the evaluation of renal, urinary, hepatic and metabolic disorders. Combur10 Test UX are test strips for single use only. Combur10 Test UX are screening tests and can aid in the diagnosis of pathological conditions. Not for self-testing. The test is intended for near-patient testing.
Device(s):	Combur10 Test UX Cat. No. 11544373170

Classification:	B
Device Group:	W0101060204 - URINE MULTI-CONSTITUENT TEST STRIPS (MANUAL) W0101060205 - URINE MULTI-CONSTITUENT TEST STRIPS (AUTOMATED)
Basic UDI-DI:	761333601676BB
Intended Purpose:	The Combur10 Test UX are test strips for the in vitro qualitative or semi-quantitative determination of pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, erythrocytes and specific gravity in urine with the Urisys 1100 urine analyzer and by visual reading. These measurements are useful in the evaluation of renal, urinary, hepatic and metabolic disorders. Combur10 Test UX are test strips for single use only. Combur10 Test UX are screening tests and can aid in the diagnosis of pathological conditions. Not for self-testing. The test is intended for near-patient testing.
Device(s):	Combur10 Test UX Cat. No. 11544373171

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Classification:	B
Device Group:	W0101060204 - URINE MULTI-CONSTITUENT TEST STRIPS (MANUAL) W0101060205 - URINE MULTI-CONSTITUENT TEST STRIPS (AUTOMATED)
Basic UDI-DI:	761333601677BD
Intended Purpose:	The Combur10 Test UX are test strips for the in vitro qualitative or semi-quantitative determination of pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, erythrocytes and specific gravity in urine with the Urisys 1100 urine analyzer and by visual reading. These measurements are useful in the evaluation of renal, urinary, hepatic and metabolic disorders. Combur10 Test UX are test strips for single use only. Combur10 Test UX are screening tests and can aid in the diagnosis of pathological conditions. Not for self-testing. The test is intended for near-patient testing.
Device(s):	Combur10 Test UX Cat. No. 11544373243

Classification:	B
Device Group:	W0101060204 - URINE MULTI-CONSTITUENT TEST STRIPS (MANUAL) W0101060205 - URINE MULTI-CONSTITUENT TEST STRIPS (AUTOMATED)
Basic UDI-DI:	761333601678BF
Intended Purpose:	The Combur10 Test UX are test strips for the in vitro qualitative or semi-quantitative determination of pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, erythrocytes and specific gravity in urine with the Urisys 1100 urine analyzer and by visual reading. These measurements are useful in the evaluation of renal, urinary, hepatic and metabolic disorders. Combur10 Test UX are test strips for single use only. Combur10 Test UX are screening tests and can aid in the diagnosis of pathological conditions. Not for self-testing. The test is intended for near-patient testing.
Device(s):	Combur10 Test UX Cat. No. 11544373343

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Classification:	B
Device Group:	W0101060204 - URINE MULTI-CONSTITUENT TEST STRIPS (MANUAL) W0101060205 - URINE MULTI-CONSTITUENT TEST STRIPS (AUTOMATED)
Basic UDI-DI:	761333601638B3
Intended Purpose:	The Combur10 Test UX are test strips for the in vitro qualitative or semi-quantitative determination of pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, erythrocytes and specific gravity in urine with the Urisys 1100 urine analyzer and by visual reading. These measurements are useful in the evaluation of renal, urinary, hepatic and metabolic disorders. Combur10 Test UX are test strips for single use only. Combur10 Test UX are screening tests and can aid in the diagnosis of pathological conditions. Not for self-testing. The test is intended for near-patient testing.
Device(s):	Combur10 Test UX Cat. No. 11544373049

Classification:	B
Device Group:	W0101060204 - URINE MULTI-CONSTITUENT TEST STRIPS (MANUAL) W0101060205 - URINE MULTI-CONSTITUENT TEST STRIPS (AUTOMATED)
Basic UDI-DI:	761333601639B5
Intended Purpose:	The Combur10 Test UX are test strips for the in vitro qualitative or semi-quantitative determination of pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, erythrocytes and specific gravity in urine with the Urisys 1100 urine analyzer and by visual reading. These measurements are useful in the evaluation of renal, urinary, hepatic and metabolic disorders. Combur10 Test UX are test strips for single use only. Combur10 Test UX are screening tests and can aid in the diagnosis of pathological conditions. Not for self-testing. The test is intended for near-patient testing.
Device(s):	Combur10 Test UX Cat. No. 11544373173

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Classification:	B
Device Group:	W0101060204 - URINE MULTI-CONSTITUENT TEST STRIPS (MANUAL) W0101060205 - URINE MULTI-CONSTITUENT TEST STRIPS (AUTOMATED)
Basic UDI-DI:	761333601640AN
Intended Purpose:	The Combur10 Test UX are test strips for the in vitro qualitative or semi-quantitative determination of pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, erythrocytes and specific gravity in urine with the Urisys 1100 urine analyzer and by visual reading. These measurements are useful in the evaluation of renal, urinary, hepatic and metabolic disorders. Combur10 Test UX are test strips for single use only. Combur10 Test UX are screening tests and can aid in the diagnosis of pathological conditions. Not for self-testing. The test is intended for near-patient testing.
Device(s):	Combur10 Test UX Cat. No. 11544373191

Classification:	B
Device Group:	W0101060204 - URINE MULTI-CONSTITUENT TEST STRIPS (MANUAL) W0101060205 - URINE MULTI-CONSTITUENT TEST STRIPS (AUTOMATED)
Basic UDI-DI:	761333602019A8
Intended Purpose:	The Combur10 Test UX are test strips for the in vitro qualitative or semi-quantitative determination of pH, leukocytes, nitrite, protein, glucose, ketones, urobilinogen, bilirubin, erythrocytes and specific gravity in urine with the Urisys 1100 urine analyzer and by visual reading. These measurements are useful in the evaluation of renal, urinary, hepatic and metabolic disorders. Combur10 Test UX are test strips for single use only. Combur10 Test UX are screening tests and can aid in the diagnosis of pathological conditions. Not for self-testing. The test is intended for near-patient testing.
Device(s):	Combur10 Test UX Cat. No. 11544373370

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

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