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 0674 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 0674 Rev. 00

Report No.: 713280340

Valid from: 2023-09-07
Valid until: 2028-09-06

Marta Carnielli
Head of Notified Body IVD

Issue date: 2023-09-07

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Classification:	Class C
Device Group:	W0101060204 - URINE MULTI-CONSTITUENT TEST STRIPS (MANUAL)
Basic UDI-DI:	761333601590AY
Intended Purpose:	The Combur5 Test HC are five-parameter test strips for in vitro semi-quantitative determination of glucose, leukocytes, nitrite, protein and erythrocytes in urine by visual reading. These measurements are useful in the evaluation of renal, urinary and metabolic disorders. Combur5 Test HC are test strips for single use only. Combur5 Test HC are screening tests for patients. The test results can aid physicians in the diagnosis of potential pathological conditions. The test is intended for self testing.
Device(s):	Combur5 Test HC, ref no.: 11896954176
The validity of this certificate depends on conditions and/or is limited to the following:	-none-

Revision History:

Rev.	Dated	Report	Description
00	2023-09-07	713280340	Initial issuance

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