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 092547 0023 Rev. 00

Manufacturer: **Roche Diabetes Care GmbH**
Sandhofer Strasse 116
68305 Mannheim
GERMANY

SRN Manufacturer: DE-MF-000006276

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 092547 0023 Rev. 00

Report No.: 713207168

Valid from: 2021-10-18
Valid until: 2026-10-17

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2021-10-18

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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No. V74 092547 0023 Rev. 00

Classification:	C
Device Group:	W0201060102 - BLOOD GLUCOSE METERS
Basic UDI-DI:	4015630GM02010X5
Intended Purpose:	The Accu-Chek Active system consists of the Accu-Chek Active meter, the Accu-Chek Active test strips, and the Accu-Chek Active control solutions. The device with the dedicated test strips is intended to quantitatively measure glucose in fresh capillary, venous, arterial and neonatal blood. It is indicated for self-testing by people with diabetes and for near-patient testing by healthcare professionals. The Accu-Chek Active system is indicated to monitor glucose in diabetes mellitus. The dedicated test strips are the Accu-Chek Active test strips.
Device(s):	Accu-Chek® Active Meter (REF no. 07135114, 07135122)

Classification:	C
Device Group:	W0101060101 - GLUCOSE TEST STRIPS
Basic UDI-DI:	4015630ST020108F
Intended Purpose:	The test strips with the dedicated blood glucose meter are intended to quantitatively measure glucose in fresh capillary, venous, arterial and neonatal blood. It is indicated for self-testing by people with diabetes and for near-patient testing by healthcare professionals. The Accu-Chek Active system is indicated to monitor glucose in diabetes mellitus. The dedicated blood glucose meter is the Accu-Chek Active blood glucose meter.
Device(s):	Accu-Chek® Active Test Strips (REF no. 07124112, 07124155, 07124210, 07124279, 07124287)

Classification:	C
Device Group:	W010106010801 - CONTROLS (BLOOD TEST STRIPS)
Basic UDI-DI:	4015630CL02010UL
Intended Purpose:	The control solution is intended for performing control tests on the dedicated test strips and blood glucose meters. It is indicated for self-testing by people with diabetes and for near-patient testing by healthcare professionals. Dedicated test strips and devices are the Accu-Chek Active test strips and the Accu-Chek Active blood glucose meter.
Device(s):	Accu-Chek® Active Control (REF no. 03146324)

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

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