



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 0029 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. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.

For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V74_092547_0029_Rev.00

Report No.: 713264213_TDA

Valid from: 2024-04-25

Valid until: 2029-04-24

Marta Carnielli
Head of Certification IVD

Issue date: 2024-04-25



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No. V74 092547 0029 Rev. 00

Classification: Class C
Device Group: W0201060102 - BLOOD GLUCOSE METERS
Basic UDI-DI: 4015630GM10108XL

Intended Purpose: The Accu-Chek Instant meter with the Accu-Chek Instant test strips is intended to quantitatively measure glucose in fresh capillary whole blood from the finger, palm, forearm, and upper arm as an aid in monitoring the effectiveness of glucose control. The Accu-Chek Instant meter with the Accu-Chek Instant test strips is intended for in vitro diagnostic self-testing by people with diabetes.
The Accu-Chek Instant meter with the Accu-Chek Instant test strips is intended for in vitro diagnostic near-patient testing by healthcare professionals in clinical settings. Venous, arterial, and neonatal blood testing is limited to healthcare professional use.

Device(s): Accu-Chek Instant meter
Ref. No.: 09221824, 09221832

Classification: Class C
Device Group: W0201060102 - BLOOD GLUCOSE METERS
Basic UDI-DI: 4015630GM09362ZQ

Intended Purpose: The Accu-Chek Instant S meter with the Accu-Chek Instant test strips is intended to quantitatively measure glucose in fresh capillary whole blood from the finger, palm, forearm, and upper arm as an aid in monitoring the effectiveness of glucose control. The Accu-Chek Instant S meter with the Accu-Chek Instant test strips is intended for in vitro diagnostic self-testing by people with diabetes.
The Accu-Chek Instant S meter with the Accu-Chek Instant test strips is intended for in vitro diagnostic near-patient testing by healthcare professionals in clinical settings. Venous, arterial, and neonatal blood testing is limited to healthcare professional use.

Device(s): Accu-Chek Instant S meter
Ref. No.: 07819463, 07819471



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No. V74 092547 0029 Rev. 00

Classification: Class C
Device Group: W0101060101 - GLUCOSE TEST STRIPS
Basic UDI-DI: 4015630ST09331AP

Intended Purpose: The Accu-Chek Instant test strips with the Accu-Chek Instant and Accu-Chek Instant S meters are indicated to quantitatively measure glucose in fresh capillary whole blood from the finger, palm, forearm, and upper arm as an aid in monitoring the effectiveness of glucosecontrol. The Accu-Chek Instant test strips with the Accu-Chek Instant and Accu-Chek Instant S meters are intended for in vitro diagnostic self- testing by people with diabetes.
The Accu-Chek Instant test strips with the Accu-Chek Instant and Accu-Chek Instant S meters are intended for in vitro diagnostic near-patient testing by healthcare professionals in clinical settings. Venous, arterial, and neonatal blood testing is limited to healthcare professional use.

Device(s): Accu-Chek Instant test strips
Ref. No.: 07819366, 07819374, 07819382, 07819404

Classification: Class C
Device Group: W010106010801 - BLOOD TEST STRIPS CONTROLS
Basic UDI-DI: 4015630CL09333WY

Intended Purpose: The Accu-Chek Instant control solution is intended for performing control tests on the Accu-Chek Instant and Accu-Chek Instant S blood glucose meters and Accu-Chek Instant test strips. It is intended for self-testing by people with diabetes and for near-patient testing by healthcare professionals.

Device(s): Accu-Chek Instant control
Ref. No.: 07869525



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No. V74 092547 0029 Rev. 00

Classification: Class C
Device Group: W010106010801 - BLOOD TEST STRIPS CONTROLS
Basic UDI-DI: 4015630LY102687X

Intended Purpose: The Accu-Chek Instant linearity test kit is intended for periodic verification of linearity of the Accu-Chek Instant and Accu-Chek Instant S systems using Accu-Chek Instant test strips. It is intended for near-patient testing by healthcare professionals only.

Device(s): Accu-Chek Instant linearity test kit
Ref. No.: 07869622

The validity of this certificate depends on conditions and/or is limited to the following: For the instrument/ meter(s) listed above, the certificate covers only the application for self-testing.

Revision History:

Rev.	Dated	Report	Description
00	2024-04-25	713264213_TDA	Initial issuance