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 0026 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 0026 Rev. 00

Report No.: 713217722

Valid from: 2022-05-27
Valid until: 2027-05-26

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-05-27

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No. V74 092547 0026 Rev. 00

Classification:	C
Device Group:	W0101060101 - GLUCOSE TEST STRIPS
Basic UDI-DI:	4015630ST020128K
Intended Purpose:	The test strips with the dedicated blood glucose meter are intended to quantitatively measure glucose in fresh capillary, venous, arterial and neonatal whole blood as an aid in monitoring the effectiveness of glucose control. They are indicated for self-testing by people with diabetes and for near-patient testing by healthcare professionals. They are intended for in vitro diagnostic use by healthcare professionals in clinical settings and by people with diabetes at home
Device(s):	Accu-Chek® Aviva Test Strips (REF 06453953, 06453961, 06453970, 06453988, 08967580, 08967598)

Classification:	C
Device Group:	W010106010801 - BLOOD TEST STRIPS CONTROLS
Basic UDI-DI:	4015630CL02012UQ
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
Device(s):	Accu-Chek® Aviva Control (REF 04455215)

Classification:	C
Device Group:	W010106010801 - BLOOD TEST STRIPS CONTROLS
Basic UDI-DI:	4015630CL06695XG
Intended Purpose:	The linearity solution is intended for performing linearity tests on the dedicated test strips and blood glucose meters. It is indicated for near-patient testing by healthcare professionals. Use only for periodic verification of linearity of Accu-Chek systems using Accu-Chek Aviva, Accu-Chek Performa and Accu-Chek Inform II test strips
Device(s):	Accu-Chek® Linearity Kit (REF 05048010)

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No. V74 092547 0026 Rev. 00

Classification:	C
Device Group:	W0101060101 - GLUCOSE TEST STRIPS
Basic UDI-DI:	4015630I202363NR
Intended Purpose:	The Accu-Chek Inform II test strips with the dedicated blood glucose meters (Accu-Chek Inform II, Accu-Chek Performa (with code chip slot), and Accu-Chek Performa Nano) are intended to quantitatively measure glucose in fresh capillary, venous, arterial and neonatal whole blood. They are indicated as an aid in monitoring the effectiveness of glucose control for self-testing by people with diabetes and for near-patient testing by healthcare professionals
Device(s):	Accu-Chek® Inform II Test Strips (REF 05942861)

Classification:	C
Device Group:	W010106010801 - BLOOD TEST STRIPS CONTROLS
Basic UDI-DI:	4015630CL02363VQ
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
Device(s):	Accu-Chek® Performa Control (REF05128030, 04861736, 05078164)

Classification:	C
Device Group:	W0101060101 - GLUCOSE TEST STRIPS
Basic UDI-DI:	4015630ST023639K
Intended Purpose:	The test strips with the dedicated blood glucose meter are intended to quantitatively measure glucose in fresh capillary, venous, arterial and neonatal whole blood as an aid in monitoring the effectiveness of glucose control. They are indicated for self-testing by people with diabetes and for near-patient testing by healthcare professionals. They are intended for in vitro diagnostic use by healthcare professionals in clinical settings and by people with diabetes at home
Device(s):	Accu-Chek® Performa Test Strips (REF 06453996, 06454003, 06454011, 06454038, 08966648, 09049851)

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

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