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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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Product Service

# EC Certificate

Full Quality Assurance System
Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

## No. V1 092547 0015 Rev. 04

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

**Facility(ies):** Roche Diabetes Care GmbH
Sandhofer Strasse 116, 68305 Mannheim, GERMANY

**Product Category(ies):** **Blood glucose measuring systems for self testing**

**Model(s):** **Blood Glucose Monitoring Systems including Meters, Test Strips, Test Cassettes, Control Solutions and In-Vitro Diagnostic Software**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V1 092547 0015 Rev. 04

**Report no.:** 713212605

**Valid from:** 2021-11-01
**Valid until:** 2024-05-26

**Date,** 2021-10-27

Christoph Dicks
Head of Certification/Notified Body


TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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