



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](http://www.tuvsud.com/ps-cert?q=cert:V1_092547_0015_Rev_04)

**Report no.:**

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**Valid from:**

2021-11-01

**Valid until:**

2024-05-26

**Date,**

2021-10-27

Christoph Dicks  
Head of Certification/Notified Body