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
ZLG-BS-245.10.07

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. 03

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. See also notes overleaf.

Report no.: 713168743

Valid from: 2019-12-03
Valid until: 2021-10-31

Date, 2019-12-03

Christoph Dicks
Head of Certification/Notified Body

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

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany