



Certificate

No. Q5 092547 0013 Rev. 01

Holder of Certificate: **Roche Diabetes Care GmbH**
Sandhofer Strasse 116
68305 Mannheim
GERMANY

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

See Scope of Certificate

Certification Mark:



Scope of Certificate: Design, manufacture and marketing of in vitro diagnostic systems used in diabetes care by blood monitoring and medical devices, including infusion/injection systems and related accessories, software, blood sampling devices, associated lancets

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). 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:Q5_092547_0013_Rev._01

Report No.: 713222669

Valid from: 2021-11-01

Valid until: 2024-10-31

Date, 2021-10-29



Christoph Dicks

Head of Certification/Notified Body