ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 092547 0013 Rev. 04

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

Certification Mark:

Scope of Certificate: **Design and Development, Manufacture and Distribution of**
- in-vitro diagnostic systems used in Diabetes Care blood monitoring
- medical devices for monitoring, infusion and injection systems and related accessories, software, and blood sampling devices with associated lancets used in the area of Diabetes Care.

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, Certification, Validation and Verification Regulations 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. 04

Report No.: 713387047

Valid from: 2025-12-15
Valid until: 2027-10-31

Date, 2025-12-15

Christoph Dicks
Head of Certification/Notified Body

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

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Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

Facility(ies):

Roche Diabetes Care GmbH
Sandhofer Strasse 116, 68305 Mannheim, GERMANY

Design and Development, and Distribution of
- in-vitro diagnostic systems used in Diabetes Care blood monitoring
- medical devices for monitoring, infusion and injection systems and related accessories, software, and blood sampling devices with associated lancets used in the area of Diabetes Care

Roche Diagnostics GmbH Diabetes Care
Sandhofer Strasse 116, 68305 Mannheim, GERMANY

Manufacture of
- in-vitro diagnostic systems used in Diabetes Care blood monitoring
- medical devices for monitoring, infusion and injection systems and related accessories, software, and blood sampling devices with associated lancets used in the area of Diabetes Care

Parameters: ./.

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