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

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

Certificate

No. Q5 102244 0001 Rev. 04

Holder of Certificate: **Roche Diagnostics, S.L.U.**
Av. de la Generalitat 171-173
08174 Sant Cugat del Vallès, Barcelona
SPAIN

Facility(ies): **Roche Diagnostics, S.L.U.**
Av. de la Generalitat 171-173, 08174 Sant Cugat del Vallès, Barcelona, SPAIN

See Scope of Certificate

Certification Mark:

Scope of Certificate: **Design, development, production and service of stand-alone software as medical device or in-vitro diagnostic medical device for diabetes care management and related diseases.**

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

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 102244 0001 Rev. 04

Report No.: ITA200220009372

Valid from: 2025-11-01
Valid until: 2028-10-31

Date, 2025-10-29

Christoph Dicks
Head of Certification/Notified Body

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