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

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

Product Service

Certificate

No. Q5 120500 0002 Rev. 00

Holder of Certificate: **ORGENTEC Diagnostika GmbH**
Carl-Zeiss-Str. 49-51
55129 Mainz
GERMANY

Facility(ies): **ORGENTEC Diagnostika GmbH**
Carl-Zeiss-Str. 49-51, 55129 Mainz, GERMANY

See Scope of Certificate

Certification Mark:

tuvsud.com/ps-cert

Scope of Certificate: **Design & development, manufacturing and distribution of in-vitro diagnostic reagents, test kits and controls for infectious diseases, sample collection device, and immunochemistry. Design & development, manufacturing, distribution and servicing of in-vitro diagnostic instruments/analysers for infectious diseases, and immunochemistry. Distribution of in-vitro diagnostic test kits and controls for immunochemistry and haematology.**

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 120500 0002 Rev. 00

Report No.: 713317921_ISO

Valid from: 2025-07-24
Valid until: 2028-07-23

Date, 2025-07-24

Christoph Dicks
Head of Certification/Notified Body

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