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

Product Service

Certificate

No. Q5 044132 0023 Rev. 03

Holder of Certificate: **EKF-diagnostic GmbH**
Ebendorfer Chaussee 3
39179 Barleben
GERMANY

Certification Mark:

TÜV SÜD
EN ISO 13485
tuvsud.com/ps-cert

Scope of Certificate:

Design and Development, Production and Distribution of In Vitro Diagnostic Reagents for Haematology and Clinical Chemistry.

Design and Development, Production, Distribution and Service of In Vitro Diagnostic Instruments for Haematology and Clinical Chemistry.

The provision of Design and Development services for In Vitro Diagnostic Reagents for Haematology and Clinical Chemistry.

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 044132 0023 Rev. 03

Report No.: 713333733_CN

Valid from: 2024-08-27
Valid until: 2025-11-22

Date, 2024-08-27

Christoph Dicks
Head of Certification/Notified Body

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

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Product Service

Certificate

No. Q5 044132 0023 Rev. 03

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):

EKF-diagnostic GmbH
Ebendorfer Chaussee 3, 39179 Barleben, GERMANY

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SensLab Gesellschaft zur Entwicklung und Herstellung bioelektrochemischer Sensoren mbH
Bautzner Straße 67, 04347 Leipzig, GERMANY

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