



Certificate

No. Q5 044132 0023 Rev. 02

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

Certification Mark:



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 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 044132 0023 Rev. 02

Report No.: 713294312_CN

Valid from: 2023-11-03
Valid until: 2025-11-22

Date, 2023-11-03

Christoph Dicks
Head of Certification/Notified Body

Certificate

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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): **EKF-diagnostic GmbH**
Ebendorfer Chaussee 3, 39179 Barleben, GERMANY

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

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

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

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