



Certificate

No. Q5 044132 0023 Rev. 00

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

Certification Mark:



Scope of Certificate: **Design and Development, Production, Distribution and Service of electrochemical and photometric in-vitro diagnostic systems for analysis of blood components**

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. 00](http://www.tuvsud.com/ps-cert?q=cert:Q5_044132_0023_Rev_00)

Report No.: 713209699

Valid from: 2021-07-01

Valid until: 2024-06-30

Date, 2021-06-21

Christoph Dicks
Head of Certification/Notified Body

Certificate

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Applied Standard(s):

EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies):

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

Design and Development, Production, Distribution and Service
of electrochemical and photometric in-vitro diagnostic systems
for analysis of blood components

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

Design and Development, Production, Distribution and Service
of electrochemical in-vitro diagnostic systems for analysis of blood
components

Parameters: ./.