



Certificate

No. Q5 049408 0045 Rev. 04

Holder of Certificate: **BAG Diagnostics GmbH**
Amtsgerichtsstr. 1-5
35423 Lich
GERMANY

Certification Mark:



Scope of Certificate: **Design and Development, Production and Distribution of In-Vitro Diagnostic Reagents for Haematology, Immunohematology, Genetic Testing and Infectious Immunology.**
Design and development, production, distribution and servicing of in vitro diagnostic instruments for Haematology, Immunohematology and Genetic Testing.
The provision of Distribution Service for In-Vitro Diagnostic reagents for Haematology.

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 049408 0045 Rev. 04](http://www.tuvsud.com/ps-cert?q=cert:Q5_049408_0045_Rev.04)

Report No.: 713306152 / 713306152-CN

Valid from: 2024-06-12

Valid until: 2027-06-11

Date, 2024-06-12

Christoph Dicks
Head of Certification/Notified Body

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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): **BAG Diagnostics GmbH**
Amtsgerichtsstr. 1-5, 35423 Lich, GERMANY

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