



Product Service

Certificate

No. Q5 120353 0003 Rev. 01

Holder of Certificate: **Gesellschaft zur Forschung, Entwicklung und Distribution von Diagnostika im Blutspendewesen mbH**

Altenhöferallee 3
60438 Frankfurt am Main
GERMANY

Certification Mark:



Scope of Certificate: **Design and development, manufacturing and distribution of in vitro diagnostic reagent kits for the detection of infectious agents.**
Design and development, manufacturing, distribution, installation and service of in vitro diagnostic instruments for the detection of infectious agents.

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 120353 0003 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:Q5_120353_0003_Rev_01)

Report No.: 713346616

Valid from: 2025-01-14

Valid until: 2028-01-13

Date, 2024-12-19

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): **Gesellschaft zur Forschung, Entwicklung und Distribution von Diagnostika im Blutspendewesen mbH**
Altenhöferallee 3, 60438 Frankfurt am Main, GERMANY

Design and development, manufacturing and distribution of in vitro diagnostic reagent kits for the detection of infectious agents.
Design and development, manufacturing, distribution, installation and service of in vitro diagnostic instruments for the detection of infectious agents.

Gesellschaft zur Forschung, Entwicklung und Distribution von Diagnostika im Blutspendewesen mbH
In der Schildwacht 13, 65933 Frankfurt am Main, GERMANY

Manufacturing, storage and distribution of in vitro diagnostic reagent kits for the detection of infectious agents.

Gesellschaft zur Forschung, Entwicklung und Distribution von Diagnostika im Blutspendewesen mbH
In der Schildwacht 13a, 65933 Frankfurt am Main, GERMANY

Storage and distribution of in vitro diagnostic reagent kits for the detection of infectious agents.

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