



Certificate

No. Q5 105845 0001 Rev. 00

Holder of Certificate: **SphingoTec GmbH**

Neuendorfstr. 15A
16761 Hennigsdorf
GERMANY

Facility(ies):

SphingoTec GmbH
Neuendorfstr. 15A, 16761 Hennigsdorf, GERMANY

See Scope of Certificate

Certification Mark:



Scope of Certificate:

Design and development, manufacturing and distribution of in-vitro diagnostic immunochemistry (immunology) reagents for measurement of blood-based biomarkers. Provision of distribution services of immunochemistry (immunology) platforms for measurement of blood-based biomarkers in near-patient and in laboratory settings

Applied Standard(s):

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

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 105845 0001 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:Q5_105845_0001_Rev._00)

Report No.: 713161826

Valid from: 2022-02-25

Valid until: 2025-02-24

Date, 2022-02-25



Christoph Dicks

Head of Certification/Notified Body