



# Certificate

No. Q5 026709 0009 Rev. 02

**Holder of Certificate:** **DIALAB Produktion und Vertrieb von chemisch-technischen Produkten und Laborinstrumenten Gesellschaft m.b.H.**

IZ-NOE Sued  
Hondastrasse, Objekt M55  
2351 Wr. Neudorf  
AUSTRIA

**Certification Mark:**



**Scope of Certificate:** Design, development, production and distribution of in-vitro diagnostic reagents and testkits in the areas of immunological detection of infectious diseases, immunochemistry/immunology/clinical chemistry biomarkers (analytes: enzymes, substrates, electrolytes reagents; controls/standards/calibrators), urinalysis, haematology, haemostasis and immuno haematology (blood grouping). Distribution of in-vitro diagnostic instruments including accessories for immunology, clinical chemistry, haematology, haemostasis and urinalysis.

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 026709 0009 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5_026709_0009_Rev.02)

**Report No.:** 713221549

**Valid from:** 2024-04-15

**Valid until:** 2027-04-14

**Date,** 2024-04-15



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):** **DIALAB Produktion und Vertrieb von chemisch-  
technischen Produkten und Laborinstrumenten  
Gesellschaft m.b.H.**  
IZ-NOE Sued, Hondastrasse, Objekt M55, 2351 Wr. Neudorf,  
AUSTRIA

See Scope of Certificate

**Parameters: ./.**