ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 079456 0006 Rev. 02

Holder of Certificate: **Hain Lifescience GmbH**
Hardwiesenstr. 1
72147 Nehren
GERMANY

Certification Mark:

Scope of Certificate: **Design and Development, Manufacturing, Servicing, Installation and Distribution of molecular biological in-vitro diagnostic devices (reagents, instruments, software) for Clinical Chemistry, Immunology, Infectious Diseases and Genetic Disorders.**
The provision of Warehousing, Installation, Maintenance and Distribution services for molecular biological in-vitro diagnostic instruments for Infectious Diseases and Genetic Disorders.

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 079456 0006 Rev. 02

Report No.: 713335673, 713335673_CN

Valid from: 2024-08-18
Valid until: 2027-08-17

Date, 2024-08-12

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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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):

Hain Lifescience GmbH
Hardwiesenstr. 1, 72147 Nehren, GERMANY

Administration, Quality Management, Technical Service, Design and Development and Manufacturing of reagents, instruments and software, Quality Control, Warehousing and Distribution of molecular biological in-vitro diagnostics reagents for Clinical Chemistry, Immunology, Infectious Diseases and Genetic Disorders.
Installation and Maintenance services for molecular biological in-vitro diagnostic instruments for Infectious Diseases and Genetic Disorders.

Hain Lifescience GmbH
Pfaffenwiesen 4, 72147 Nehren, GERMANY

Manufacturing of molecular biological in-vitro diagnostic reagents for Clinical Chemistry, Immunology, Infectious Diseases and Genetic Disorders.

Hain Lifescience GmbH
Pfaffenwiesen 10, 72147 Nehren, GERMANY

Warehousing, Marketing, Distribution and IT of molecular biological in-vitro diagnostic Reagents and Instruments for Clinical Chemistry, Immunology, Infectious Diseases and Genetic Disorders.
The provision of Warehousing and Distribution services for molecular biological in-vitro diagnostic instruments for Infectious Diseases and Genetic Disorders.

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