



Certificate

No. Q5 079456 0006 Rev. 00

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

Certification Mark:



Scope of Certificate: **Design, 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 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 079456 0006 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:Q5_079456_0006_Rev._00)

Report No.: 713217361

Valid from: 2021-08-18

Valid until: 2024-08-17

Date, 2021-08-18



Christoph Dicks
Head of Certification/Notified Body

Certificate

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

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 diagnostic Reagents for Clinical Chemistry, Immunology, 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
Reutlinger Straße 97, 72147 Nehren, GERMANY

Warehousing, Marketing, Distribution, IT, as well as Technical Service and Quality Control of molecular biological in-vitro diagnostic Instruments for Clinical Chemistry, Immunology, Infectious Diseases and Genetic Disorders

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