



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

Certificate

No. Q5 005092 0001 Rev. 02

Holder of Certificate: **Molecular Health GmbH**

Kurfürsten-Anlage 21
69115 Heidelberg
GERMANY

Facility(ies):

Molecular Health GmbH

Kurfürsten-Anlage 21, 69115 Heidelberg, GERMANY

See Scope of Certificate

Certification Mark:



Scope of Certificate:

Design, Development and Manufacture of in-vitro-diagnostic software systems for molecular and genetic testing based on data from Next Generation Sequencing or other technologies to support patient management decisions for constitutional diseases or cancer and provision of related services.

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

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 005092 0001 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5_005092_0001_Rev.02)

Report No.: 713337206

Valid from: 2025-01-22

Valid until: 2028-01-21

Date, 2024-12-16

Christoph Dicks

Head of Certification/Notified Body