MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 005092 0002 Rev. 01

Certificate Holder: **Molecular Health GmbH**
Kurfürsten-Anlage 21
69115 Heidelberg
GERMANY

Certification Mark:

Scope of Certificate: **Design and Development, Manufacture, Installation, and Servicing of In-Vitro Diagnostic Software used in Genetic Testing for the Diagnosis of Hereditary Diseases or Predispositions to a Medical Condition or a Disease and Prediction of Treatment Response including Point of Care In-Vitro Diagnostic Medical Devices**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, Brazil ANVISA, Health Canada, USA FDA, MHLW / PMDA. See attached for listing of specific regulatory requirements.**

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website https://www.tuev-sued.de/product-testing/certificates

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

DUNS No: **55-107-6396**

Effective Date: **2019-04-29**

Expiry Date: **2022-04-28**

Date of Issue: 2019-06-06

(Dawn M. Tibodeau)
Manager, Certification Body MHS

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Regulatory Requirements: **Audit/Certification Criteria**

Australia
Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1

Brazil
- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

Canada
- Medical Device Regulations SOR/98-282, Part 1

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820

Japan
- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

Facility(ies): Molecular Health GmbH
Kurfürsten-Anlage 21, 69115 Heidelberg, GERMANY

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