



America

# CERTIFICATE

No. QS6 005092 0002 Rev. 03

**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):**

**Japan 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. For details and certificate validity see:

[www.tuvsud.com/ps-cert?q=cert:QS6\\_005092\\_0002\\_Rev.03](http://www.tuvsud.com/ps-cert?q=cert:QS6_005092_0002_Rev.03)

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

**REPs Facility ID:**

**F003903**

**Report No.:**

**713337206**

**Effective Date:**

**2025-04-29**

**Expiry Date:**

**2028-04-28**

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**Date of Issue:** 2025-02-27

( Renee Walker )  
Director, US Certification Body, MHS



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No. QS6 005092 0002 Rev. 03

**Regulatory Requirements:**      **Audit/Certification Criteria**

**Japan**

- MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)
- Japan PMD Act (as applicable)

**Facility(ies):**

**Molecular Health GmbH**

Kurfürsten-Anlage 21, 69115 Heidelberg, GERMANY

**Facility Scopes:**

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  
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