



America

# CERTIFICATE

No. QS6 055003 0015 Rev. 01

**Certificate Holder:** **Haselmeier GmbH**  
 Vaihinger Strasse 48  
 70567 Stuttgart  
 GERMANY

**Certification Mark:**



**Scope of Certificate:** **Design and Development, Manufacture and Distribution of Pen Injectors and Autoinjectors for Single and Multiple Use**

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

**Regulatory Authority(ies):** **Australia TGA, Brazil ANVISA, Health Canada. 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 [www.tuvsud.com/ps-cert](http://www.tuvsud.com/ps-cert)  
 TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

**REPs Facility ID:** **F002948**

**Effective Date:** **2023-01-25**

**Expiry Date:** **2026-01-24**

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**Date of Issue:** 2023-03-02

( Renee Walker )  
 Director, US Certification Body, MHS



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**Regulatory Requirements:      Audit/Certification Criteria**

**Australia**

Therapeutic Goods (Medical Devices) Regulations 2002  
 - Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

**Brazil**

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

**Canada**

- Medical Device Regulations – Part 1- SOR 98/282

**Facility(ies):**

Haselmeier GmbH  
 Vaihinger Strasse 48, 70567 Stuttgart, GERMANY

Haselmeier GmbH  
 Siemensstr. 5, 74722 Buchen, GERMANY

Haselmeier GmbH  
 Siemensstraße 12, 74722 Buchen, GERMANY

**Facility Scopes:**

**Haselmeier GmbH**

Vaihinger Strasse 48, 70567 Stuttgart, GERMANY

Design and Development, Production and Distribution of Pen Injectors and Autoinjectors for Single and Multiple Use  
 REPs Facility ID: F002948

**Haselmeier GmbH**

Siemensstr. 5, 74722 Buchen, GERMANY

Production and Distribution of Pen Injectors and Autoinjectors for Single and Multiple Use  
 REPs Facility ID: F002949

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**Haselmeier GmbH**

Siemensstraße 12, 74722 Buchen, GERMANY

Prototype Construction Area Conditioned Measuring Room  
(Testing of First Sample) and Storage Area for Packaging  
Material and Final Product  
REPs Facility ID: F002949

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