



America

CERTIFICATE

No. QS6 055003 0015 Rev. 02

Certificate Holder: Haselmeier GmbH
Schelmenwasenstr. 14
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, 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. For details and certificate validity see:

www.tuvsud.com/ps-cert?q=cert:QS6_055003_0015_Rev.02

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

REPs Facility ID: F002948
Report No.: 713317719
Effective Date: 2024-02-06
Expiry Date: 2026-01-24

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Date of Issue: 2024-02-12

(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

Canada

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

Facility(ies):

Haselmeier GmbH

Schelmenwasenstr. 14, 70567 Stuttgart, GERMANY

Haselmeier GmbH

Siemensstr. 5, 74722 Buchen, GERMANY

Haselmeier GmbH

Siemensstraße 12, 74722 Buchen, GERMANY

Facility Scopes:

Haselmeier GmbH

Schelmenwasenstr. 14, 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

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