



# Certificate

No. Q5 055003 0013 Rev. 04

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

**Certification Mark:**



**Scope of Certificate:** **Design and Development, Production and Distribution of pen injectors and auto-injectors for single and multiple use, of connected pen injectors, connected accessories and software as medical device**

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 and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 055003 0013 Rev. 04](http://www.tuvsud.com/ps-cert?q=cert:Q5_055003_0013_Rev.04)

**Report No.:** 713274055

**Valid from:** 2023-07-31

**Valid until:** 2026-05-31

**Date,** 2023-08-01



Christoph Dicks  
Head of Certification/Notified Body

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**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems -  
Requirements for regulatory purposes  
(ISO 13485:2016)  
DIN EN ISO 13485:2016

**Facility(ies):** **Haselmeier GmbH**  
Vaihinger Strasse 48, 70567 Stuttgart, GERMANY

Design and Development and distribution of pen injectors and auto-injectors for single and multiple use, of connected pen injectors, connected accessories and software as medical device

**Haselmeier GmbH**  
Siemensstr. 5, 74722 Buchen, GERMANY

Production and distribution of pen injectors and auto-injectors for single and multiple use, of connected pen injectors, connected accessories and software as medical device

**Haselmeier GmbH**  
Siemensstraße 12, 74722 Buchen, GERMANY

Production and distribution of pen injectors and auto-injectors for single and multiple use, of connected pen injectors, connected accessories and software as medical device