



Certificate

No. Q5 055003 0013 Rev. 05

Holder of Certificate: **Haselmeier GmbH**
Schelmenwasenstr. 14
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. 05](http://www.tuvsud.com/ps-cert?q=cert:Q5_055003_0013_Rev.05)

Report No.: 713317719

Valid from: 2024-02-16

Valid until: 2026-05-31

Date, 2024-02-16



Christoph Dicks
Head of Certification/Notified Body

Certificate

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Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies): **Haselmeier GmbH**
Schelmenwasenstr. 14, 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

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