



Product Service

Certificate

No. Q5 054875 0002 Rev. 02

Holder of Certificate: **Ypsomed AG**
Brunnmattstrasse 6
3401 Burgdorf
SWITZERLAND

Certification Mark:



Scope of Certificate: **Design and Development, Manufacture and Distribution of Injection Systems, Infusion Systems, and Related Software**

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, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 054875 0002 Rev. 02](http://www.tuvsud.com/ps-cert?q=cert:Q5_054875_0002_Rev_02)

Report No.: 713339432

Valid from: 2025-04-23

Valid until: 2028-04-22

Date, 2025-02-24

Christoph Dicks
Head of Certification/Notified Body



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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): **Ypsomed AG**
Brunnmattstrasse 6, 3401 Burgdorf, SWITZERLAND

Design and Development, Manufacture and Distribution of
Injection Systems, Infusion Systems, and Related Software

Ypsomed AG
Buchmattstrasse 100, 3401 Burgdorf, SWITZERLAND

Manufacture and Distribution of Injection Systems and Infusion
Systems

Ypsomed AG
Lochbachstrasse 26, 3401 Burgdorf, SWITZERLAND

Manufacture and Distribution of Injection Systems and Infusion
Systems

Ypsomed AG
Weissensteinstrasse 26, 4503 Solothurn, SWITZERLAND

Design and Development, Manufacture and Distribution of
Injection Systems, Infusion Systems, and Related Software

Ypsomed Software S.L.U.
Calle Rambla Catalunya 18, 08007 Barcelona, SPAIN

Design and Development, Manufacture, and Distribution of
Software

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