



America

CERTIFICATE

No. QS6 054875 0001 Rev. 02

Certificate Holder: Ypsomed AG
Brunnmattstrasse 6
3401 Burgdorf
SWITZERLAND

Certification Mark:



Scope of Certificate: Design and Development, Manufacture and Distribution of Infusion Pumps, Sterile Infusion Sets for Infusion Pumps, Active and Non-Active Injection Pens, Sterile Pen Needles for Subcutaneous Injection, Software Integrated in Infusion Pump and related End User Software

Standard(s): ISO 13485:2016

Regulatory Authority(ies): Australia TGA, Brazil ANVISA, Health Canada, USA FDA, MHLW / PMDA. 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
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: F004215
Effective Date: 2022-10-04
Expiry Date: 2025-03-27

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Date of Issue: 2022-10-11

(Renee Walker)
Manager, US Certification Body,
Medical and Health Services

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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

Japan

- MHLW Ministerial Ordinance 169, Article 4 to Article 68
 - PMD Act

United States

- 21 CFR Part 803
 - 21 CFR Part 806
 - 21 CFR Part 807 – Subparts A to D
 - 21 CFR Part 820

Facility(ies):

Ypsomed AG
 Brunnmattstrasse 6, 3401 Burgdorf, SWITZERLAND

Ypsomed AG
 Buchmattstrasse 100, 3401 Burgdorf, SWITZERLAND

Ypsomed AG
 Lochbachstrasse 26, 3401 Burgdorf, SWITZERLAND

Ypsomed AG
 Weissensteinstrasse 26, 4503 Solothurn, SWITZERLAND

Ypsomed Produktion GmbH
 Ludwig-Bölkow-Str. 15, 19061 Schwerin, GERMANY

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Facility Scopes:

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Ypsomed AG

Lochbachstrasse 26, 3401 Burgdorf, SWITZERLAND

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Ypsomed AG

Weissensteinstrasse 26, 4503 Solothurn, SWITZERLAND

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Ypsomed Produktion GmbH

Ludwig-Bölkow-Str. 15, 19061 Schwerin, GERMANY

Design and Development, Manufacture and Distribution
of Sterile Infusion Sets for Infusion Pumps and Active
and Non-Active Injection Pens

REPs Facility ID: F006188

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Medical and Health Services