



America

# CERTIFICATE

No. QS6 054875 0001 Rev. 03

**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, Sterile Reservoirs for Infusion Pumps, 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](http://www.tuvsud.com/ps-cert)

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

**REPs Facility ID:**

**F004215**

**Effective Date:**

**2023-02-15**

**Expiry Date:**

**2025-03-27**

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**Date of Issue:** 2023-03-03

( 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

### 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:

### Ypsomed AG

Brunnmattstrasse 6, 3401 Burgdorf, SWITZERLAND

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, Sterile Reservoirs for Infusion Pumps, Software Integrated in Infusion Pump and related End User Software  
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### Ypsomed AG

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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, Active and Non-Active Injection  
Pens and Sterile Reservoirs for Infusion Pumps  
REPs Facility ID: F006188

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