MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 054875 0001 Rev. 00

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 https://www.tuev-sued.de/product-testing/certificates

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

DUNS No: **48-174-2760**

Effective Date: **2019-08-07**

Expiry Date: **2022-03-27**

Date of Issue: 2019-09-19

Dawn Tibodeau

(Dawn M. Tibodeau)
Manager, Certification Body MHS

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Regulatory Requirements: **Audit/Certification Criteria**

Australia
Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1

Brazil
- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

Canada
- Medical Device Regulations SOR/98-282, Part 1

United States
- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820

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

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

Date of Issue: 2019-09-19

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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, Software Integrated in Infusion Pump and related End User Software
DUNS No: 48-174-2760

Ypsomed AG
Buchmattstrasse 100, 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, Software Integrated in Infusion Pump and related End User Software
DUNS No: 48-174-2760

Ypsomed AG
Lochbachstrasse 26, 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, Software Integrated in Infusion Pump and related End User Software
DUNS No: 48-174-2760

Ypsomed AG
Weissensteinstrasse 26, 4503 Solothurn, 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, Software Integrated in Infusion Pump and related End User Software
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Dawn Tibodeau

(Dawn M. Tibodeau)
Manager, Certification Body MHS

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