



# MDSAP

Medical Device Single Audit Program



America

## CERTIFICATE

No. QS6 129096 0003 Rev. 01

**Certificate Holder:** mylife Diabetes Care AG  
Lyssachstrasse 40  
3400 Burgdorf  
SWITZERLAND

**Certification Mark:**



**Scope of Certificate:** Design, Development, and Distribution of Infusion Pumps, Sterile Infusion Sets for Infusion Pumps, Sterile Reservoirs for Infusion Pumps, Diabetes Therapy Related Software, and Manufacture of Infusion Pumps and Diabetes Therapy Related Software

**Standard(s):** ISO 13485:2016

**Regulatory Authority(ies):** Australia TGA, Health Canada, USA FDA. 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. For details and certificate validity see:

[www.tuvsud.com/ps-cert?q=cert:QS6\\_129096\\_0003\\_Rev.01](http://www.tuvsud.com/ps-cert?q=cert:QS6_129096_0003_Rev.01)

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

**REPs Facility ID:** F008050  
**Report No.:** 713391839  
**Effective Date:** 2026-03-26  
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( Renee Walker )  
Director, US Certification Body, MHS



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No. QS6 129096 0003 Rev. 01

**Regulatory Requirements:     Audit/Certification Criteria**

**Australia**

- Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

**Canada**

- Medical Device Regulations – Part 1- SOR 98/282

**United States**

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

**Facility(ies):**

**mylife Diabetes Care AG**

Lyssachstrasse 40, 3400 Burgdorf, SWITZERLAND

**mylife Diabetes Care AG**

Buchmattstrasse 100, 3400 Burgdorf, SWITZERLAND

**Facility Scopes:**

**mylife Diabetes Care AG**

Lyssachstrasse 40, 3400 Burgdorf, SWITZERLAND

Design, Development and Distribution of Infusion Pumps, Sterile Infusion Sets for Infusion Pumps, Sterile Reservoirs for Infusion Pumps; Design, Development and Manufacture of Diabetes Therapy Related Software

REPs Facility ID: F008050

**mylife Diabetes Care AG**

Buchmattstrasse 100, 3400 Burgdorf, SWITZERLAND

Manufacture and Distribution of Infusion Pumps

REPs Facility ID: F008050

( Renee Walker )  
 Director, US Certification Body, MHS