



America

CERTIFICATE

No. QS6 011634 0208 Rev. 02

Certificate Holder:
medela 

Medela AG
Lättichstrasse 4b
6340 Baar
SWITZERLAND

Certification Mark:



Scope of Certificate:

Design and Development, Production, Distribution and Service of Breast Pump Systems, Breastfeeding Products, Body Fluid and Vacuum Aspirator Systems and Vacuum Assisted Wound Closure Systems

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:

F001274

Effective Date:

2022-01-20

Expiry Date:

2025-01-03

Page 1 of 3

Date of Issue: 2022-01-26

(Michael Ogunleye)
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):

Medela AG
 Lättichstrasse 4b, 6340 Baar, SWITZERLAND

Medela AG
 Sennweidstrasse 30, 6312 Steinhausen, SWITZERLAND

Medela AG
 Turmstrasse 30, 6312 Steinhausen, SWITZERLAND

Medela AG
 Lättichstrasse 7, 6340 Baar, SWITZERLAND

Page 2 of 3

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Facility Scopes:

Medela AG

Lättichstrasse 4b, 6340 Baar, SWITZERLAND

Headquarters (Administration, Resource Management)
Quality Management Department (CAPA, Document Control, Change Control, Regulatory, Post Market Surveillance), Design and Development
REPs Facility ID: F001274

Medela AG

Sennweidstrasse 30, 6312 Steinhausen, SWITZERLAND

Manufacturing Site; Incoming Inspection, Packaging, Warehouse Components and Finished Goods, Logistic
REPs Facility ID: F002183

Medela AG

Turmstrasse 30, 6312 Steinhausen, SWITZERLAND

Manufacturing Site; Assembly of Health Care and Breastfeeding Devices and Assembly of Accessories Kits
REPs Facility ID: F002183

Medela AG

Lättichstrasse 7, 6340 Baar, SWITZERLAND

Purchasing, Supplier Quality, Customer Service including Service/ Repair
REPs Facility ID: F001274

Page 3 of 3

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