



America

CERTIFICATE

No. QS6 011634 0208 Rev. 04

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, Japan MHLW / PMDA, 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 011634 0208 Rev. 04](http://www.tuvsud.com/ps-cert?q=cert:QS6_011634_0208_Rev.04)

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

REPs Facility ID:

F001274

Report No.:

713294174

Effective Date:

2023-10-05

Expiry Date:

2025-01-03

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Date of Issue: 2023-10-18

(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. 665/2022 - Good Manufacturing Practices
 - RDC ANVISA n. 551/2021
 - RDC ANVISA n. 67/2009 - Vigilance

Canada

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

Japan

- MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)
 - Japan PMD Act (as applicable)

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

Lättichstrasse 7, 6340 Baar, SWITZERLAND

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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, Purchasing, Supplier Quality, Customer Service
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: F001274

Medela AG

Lättichstrasse 7, 6340 Baar, SWITZERLAND

Manufacturing Site; Service / Repair, Assembly of Healthcare and Breastfeeding Devices and Assembly of Accessories Kits
REPs Facility ID: F001274

(Renee Walker)
Director, US Certification Body, MHS