



CERTIFICATE

No. QS6 032736 0035 Rev. 06

Certificate Holder: **Medela LLC**
1101 Corporate Drive
McHenry IL 60050
USA

Certification Mark:



Scope of Certificate: **Design and Development, Production, Distribution and / or Servicing of Breast Feeding Pump Systems, Infant Feeding Devices, Enteral Feeding Devices, Breastfeeding Products;**

Servicing of Suction Pumps and Weigh Scales;

Distribution of Suction Pumps and Weigh Scales for Medical Applications

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_032736_0035_Rev.06

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

REPs Facility ID: **F001275**
Report No.: **72198000**
Effective Date: **2024-10-15**
Expiry Date: **2027-10-14**

Page 1 of 3

Date of Issue: 2024-08-21

(Renee Walker)
Director, US Certification Body, MHS

CERTIFICATE

No. QS6 032736 0035 Rev. 06

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 LLC

1101 Corporate Drive, McHenry IL 60050, USA

Medela LLC

2768 Spectrum Drive, Elgin IL 60124, USA

Page 2 of 3

Date of Issue: 2024-08-21



(Renee Walker)
Director, US Certification Body, MHS

CERTIFICATE

No. QS6 032736 0035 Rev. 06

Facility Scopes:

Medela LLC

1101 Corporate Drive, McHenry IL 60050, USA

Design and Development, Production, Distribution, and / or Servicing of Breast Feeding Pump Systems, Infant Feeding Devices, Enteral Feeding Devices, Breastfeeding Products;

Servicing of Suction Pumps and Weigh Scales;

Distribution of Suction Pumps and Weigh Scales

REPs Facility ID: F001275

Medela LLC

2768 Spectrum Drive, Elgin IL 60124, USA

Distribution of Breast Feeding Pump Systems, Infant Feeding Devices, Enteral Feeding Devices, Breastfeeding Products, Suction Pumps, and Weigh Scales

REPs Facility ID: F001275



(Renee Walker)
Director, US Certification Body, MHS