



America

# CERTIFICATE

No. QS6 032736 0035 Rev. 02

**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, Weigh Scales and Phototherapy Devices; Distribution of Suction Pumps and Weigh Scales for Medical Applications**

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

**Regulatory Authority(ies):** **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. Validity of this certificate can be obtained by visiting the website [www.tuvsud.com/ps-cert](http://www.tuvsud.com/ps-cert)  
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

**REPs Facility ID:** **F001275**

**Effective Date:** **2022-02-09**

**Expiry Date:** **2022-11-15**

Page 1 of 2

**Date of Issue:** 2022-02-10

( Michael Ogunleye )  
Manager, US Certification Body,  
Medical and Health Services



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**Regulatory Requirements: Audit/Certification Criteria**

**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):**

Medela LLC  
1101 Corporate Drive, McHenry IL 60050, USA

Medela LLC  
2768 Spectrum Drive, Elgin IL 60124, USA

**Facility Scopes:**

**Medela LLC**

1101 Corporate Drive, McHenry IL 60050, USA

Design and Development, Production, Distribution, and / or Servicing of Breast Feeding Pumps, Infant Feeding Devices, Enteral Feeding Devices, Ancillary Maternity Products and Accessories; Servicing of Suction Pumps, Weigh Scales, and Phototherapy Devices; Distribution of Suction Pumps and Weigh Scales

REPs Facility ID: F001275

**Medela LLC**

2768 Spectrum Drive, Elgin IL 60124, USA

Distribution of Breast Feeding Pumps, Infant Feeding Devices, Enteral Feeding Devices, Ancillary Maternity Products and Accessories, Suction Pumps, and Weigh Scales

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Page 2 of 2

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