

EC DECLARATION OF CONFORMITY

Manufacturer's Name: Medela AG
Manufacturer's Address: Lättichstrasse 4b, (formerly 6341 Baar) 6340 Baar, Switzerland
Single Registration Number (SRN): CHRN-MF-20000112 (Medela AG SRN manufacturer)
Authorised Representative's Name: Medela Medizintechnik GmbH & Co Handels KG
Authorised Representative's Address: Georg-Kollmannsberger-Str. 2, 85386 Eching, Germany
AR's Single Registration Number (SRN): DE-AR-000008746 (Medela Germany AR SRN)

We declare under our sole responsibility as manufacturer that the Disposable Collection System of Class I according to rules set out in Annex VIII – see attached list, to which this declaration relates are in conformity with the provisions of the REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL.

Product and Trade Name: Disposable Collection System
Product Category: Body Fluid- and Vacuum Aspirator Systems, Accessories
Intended Purpose: The Medela Disposable Collection System is suitable for the safe collection and disposal of suctioned fluids.
Common Specifications used: Not applicable

Conformity Assessment Route: The medical devices are in conformity with the GENERAL SAFETY AND PERFORMANCE REQUIREMENTS of Annex I of the REGULATION (EU) 2017/745. The conformity assessment procedure was performed according to Annex IX (for class I).

ISO Certificate: ISO 13485 Certificate: No. Q5 011634 0205

This declaration of conformity is valid as long as the issued ISO certificate is valid.

The medical devices covered by the present declaration are also in conformity with relevant Union legislation that provides for the issuing of an EU declaration of conformity.

Reference	EU Directives/Regulations
2011/65/EU	Restriction of use of certain Hazardous Substances in electrical and electronic equipment Directive

Authorised Signatories:



Annette Brüls, CEO



Bianca Hedari, Director Quality CH

This Declaration of Conformity is effective from: 2022-03-28

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Article No.	Description	Class	Classifi- cation Rule	GMDN	CND- EMDN	Basic UDI	Scope of Application
PC-Jars							
077.0082 (K10021893)	1.5 L Suction Jar for DCS	I	1	34858	A06030401	07612367rvbnaeQL	All production
077.0085 (K10021896)	2.5 L Suction Jar for DCS	I	1	34858	A06030401	07612367rvbnaeQL	All production
Locking Clasp							
077.0102	Locking Clasp DCS	I	1	34858	A0701	07612367rvbnaeQL	All production
Liners							
077.0083 (K10021894)	1.5 l Suction bag	I	1	34858	A06030499	07612367rvbnaeQL	All production
077.0084 (K10021895)	1.5 l Suction bag with solidifier	I	1	34858	A06030499	07612367rvbnaeQL	All production
077.0086 (K10021897)	2.5 l Suction bag	I	1	34858	A06030499	07612367rvbnaeQL	All production
077.0087 (K10021898)	2.5 l Suction bag with solidifier	I	1	34858	A06030499	07612367rvbnaeQL	All production
101032951	Disposable liner, 1.5 L with solidifier	I	1	34858	A06030499	07612367rvbnaeQL	All production
AXS Universal Liner Sets							
077.0194	AXS Universal Liner Set	I	1	34858	A06030499	07612367rvbnaeQL	All production
101035340	AXS Universal Liner Set with Solidifier	I	1	34858	A06030499	07612367rvbnaeQL	All production
Specimen Cup							
077.0094	Specimen Cup for DCS	I	1	34858	A06030401	07612367rvbnaeQL	All production
Coupling Pieces							
077.0101	Angle piece orange DCS	I	1	34858	A0701	07612367rvbnaeQL	All production
077.0100	Angle piece yellow DCS	I	1	34858	A0701	07612367rvbnaeQL	All production
077.0097	Y-piece 7/5 mm Disposable System	I	1	34858	A0701	07612367rvbnaeQL	All production
077.0098	Y-piece 7 mm Disposable System	I	1	34858	A0701	07612367rvbnaeQL	All production
077.0095 (K10021188)	Serial connection vacuum	I	1	34858	A0701	07612367rvbnaeQL	All production
077.0158 (K10021885)	Serial connectors, 34 cm tube	I	1	34858	A0701	07612367rvbnaeQL	All production
077.0160	Serial connection, 34cm tube	I	1	34858	A0701	07612367rvbnaeQL	All production



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

Certificate

No. Q5 011634 0205 Rev. 06

Holder of Certificate:
medela 

Medela AG
Lättichstrasse 4b
6340 Baar
SWITZERLAND

Certification Mark:



Scope of Certificate:

Design and Development, production, distribution and service of non sterile breast pump systems, sterile breastfeeding products, body-fluid and vacuum aspirator systems and vacuum assisted wound closure systems

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 011634 0205 Rev. 06

Report No.: 713334116

Valid from: 2025-01-12

Valid until: 2028-01-11

Date, 2024-12-18

Christoph Dicks

Head of Certification/Notified Body



Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00



Product Service

Certificate

No. Q5 011634 0205 Rev. 06

Applied Standard(s): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems -
Requirements for regulatory purposes

Facility(ies): **Medela AG**
Lättichstrasse 4b, 6340 Baar, SWITZERLAND

Design and Development of non sterile breast pump systems,
sterile breastfeeding products, body-fluid and vacuum aspirator
systems and vacuum assisted wound closure systems

Medela AG
Lättichstrasse 7, 6340 Baar, SWITZERLAND

Production and service of non sterile breast pump systems, sterile
breastfeeding products, body-fluid and vacuum aspirator systems
and vacuum assisted wound closure systems

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