

EC DECLARATION OF CONFORMITY

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

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 on the following page, 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 ISO certificate is valid.

Authorised Signatories:



Annette Brüls, CEO *



Bianca Hedari, Director Quality CH

This Declaration of Conformity is effective from: 2021-May-17

*Thomas Ertl, COO in representation of Annette Brüls.

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Article No.	Description	Class	Classification 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