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THE SCIENCE OF CARE™

EU DECLARATION OF CONFORMITY

Manufacturer's Name:	Medela AG
Manufacturer's Address:	Lättichstrasse 4b, 6340 Baar, Switzerland
Single Registration Number (SRN):	*CHRN-MF-20000112 (EU) / CH-MF-000018913 (CH)*
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 Connectors and Tubing 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:	Connectors and Tubing
Device Category/Group:	Body Fluid- and Vacuum Aspirator Systems, Accessories
Intended Purpose:	The silicone/PVC tubes and connectors are intended to be connected to a vacuum-producing medical device, medical equipment or a medical fluid collection system to channel fluid removed from patients
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 Article 52(7) (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, Global Senior Director Quality CH

This Declaration of Conformity is effective from: 2024-03-27

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Article No.	Description	Class	Classification Rule	GMDN	EMDN	Basic UDI	Scope of Application
Disposable PVC-Tubing							
077.0952	Disposable tube, 180cm	I	1	16779	A060102	07612367mjvfhINN	All production
077.0963	Disposable tube, 200cm, 10-14mm	I	1	16779	A060102	07612367mjvfhINN	All production
Reausable Silicone-Tubing							
077.0154 (K10021878)	Vacuum tube with coupling piece	I	1	42834	A060102	07612367mjvfhINN	All production
077.0185 (K10026130)	Silicone tube, ID 7mm, 60cm, 1 coupling piece with 90°	I	1	42834	A060102	07612367mjvfhINN	All production
077.0189	Silicone tube, ID 7mm, 300cm, 2 coupling pieces	I	1	42834	A060102	07612367mjvfhINN	All production
077.0900	Silicone tube, ID 7mm, 25m	I	1	42834	A060102	07612367mjvfhINN	All production
077.0901	Silicone tube, ID 7mm, 100cm	I	1	42834	A060102	07612367mjvfhINN	All production
077.0902	Silicone tube, ID 7mm, 200cm	I	1	42834	A060102	07612367mjvfhINN	All production
077.0905	Silicone tube, ID 7mm, 500cm	I	1	42834	A060102	07612367mjvfhINN	All production
077.0911	Silicone tube, ID 7mm, 33cm, 1 coupling piece	I	1	42834	A060102	07612367mjvfhINN	All production
077.0912	Silicone tube, ID 7mm, 60cm, 1 coupling piece	I	1	42834	A060102	07612367mjvfhINN	All production
077.0913	Silicone tube, ID 7mm, 100cm, 1 coupling piece	I	1	42834	A060102	07612367mjvfhINN	All production
077.0921	Silicone tube, ID 7mm, 30cm, 2 coupling pieces	I	1	42834	A060102	07612367mjvfhINN	All production
077.0922 (K10026804)	Silicone tube, ID 7mm, 60cm, 2 coupling pieces	I	1	42834	A060102	07612367mjvfhINN	All production
077.0931	Silicone tube, ID 7mm, 25cm, 1 coupling piece 90°	I	1	42834	A060102	07612367mjvfhINN	All production
077.0961	Silicone tube, ID 6.5mm, 180cm, 1 coupling piece	I	1	42834	A060102	07612367mjvfhINN	All production
077.0970	Silicone tube, ID 5mm, 25m	I	1	42834	A060102	07612367mjvfhINN	All production
077.0051	Silicone tubing, d6.5x11.5mm, 2m	I	1	42834	A060102	07612367mjvfhINN	All production
077.0052	Silicone tubing, d6.5x11.5mm, 25m	I	1	42834	A060102	07612367mjvfhINN	All production
077.0053	Silicone tubing, d6.5x11.5mm, 32cm	I	1	42834	A060102	07612367mjvfhINN	All production
077.0054	Silicone tubing, d6.5x11.5mm, 50cm	I	1	42834	A060102	07612367mjvfhINN	All production
077.0055	Silicone tubing, d6.5x11.5mm, 120cm	I	1	42834	A060102	07612367mjvfhINN	All production
077.0056	Silicone tubing, d6.5x11.5mm, 150cm	I	1	42834	A060102	07612367mjvfhINN	All production
077.0164	Silicone tubing, d6.5x11.5mm, 3m	I	1	42834	A060102	07612367mjvfhINN	All production
Connectors							
077.0161	Coupling piece 5mm	I	1	64108	A070199	07612367mjvfhINN	All production
077.1017	Double conical coupling piece	I	1	16779	A070199	07612367mjvfhINN	All production
077.1018	Coupling piece	I	1	64108	A070199	07612367mjvfhINN	All production
077.1019	Coupling piece 90°	I	1	64108	A070199	07612367mjvfhINN	All production
077.1020	Y-piece	I	1	16779	A070199	07612367mjvfhINN	All production
Change over valve							
077.0561	Change over valve	I	1	64108	A070199	07612367mjvfhINN	All production
077.0563 (K10021882)	Change over valve set*	I	1	64108	A070199	07612367mjvfhINN	All production

*Note: This is not a set of single sales articles. Articles are packaged together.