

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 Retainer 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: Retainer
Product Category: Body Fluid- and Vacuum Aspirator Systems, Accessories
Intended Purpose: Retainers are intended to hold the canisters or tubing in place.
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).

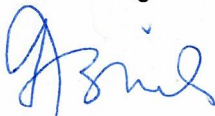
ISO Certificate: ISO 13485 Certificate: No. Q5 011634 0205

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

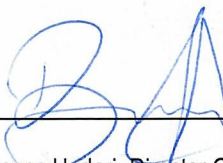
The medical devices covered by the present declaration are also in conformity with relevant Union legislation that provides for the issuing of an EU declaration of conformity.

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, Director Quality CH

This Declaration of Conformity is effective from: 2022-01-31

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Article No.	Description	Class	Classification Rule	GMDN	CND-EMDN	Basic UDI	Scope of Application
Clamp holder							
077.0521 (K10002819)	Clampholder	I	1	42446	A0680	07612367uwaovjUD	All production
Brackets							
077.0192	Wall adapter	I	1	42446	A0680	07612367uwaovjUD	All production
077.0523	Wall bracket single	I	1	42446	A0680	07612367uwaovjUD	All production
077.0526	Holder for 1L/1.5L jar, left	I	1	42446	A0680	07612367uwaovjUD	All production
077.0527	Holder for 1L/1.5L jar, right	I	1	42446	A0680	07612367uwaovjUD	All production
077.0528	Holder for 2L/2.5L jar, left	I	1	42446	A0680	07612367uwaovjUD	All production
077.0529	Holder for 2L/2.5L jar, right	I	1	42446	A0680	07612367uwaovjUD	All production
Tubing Holder							
077.0751	Tubing holder left side	I	1	42446	A0680	07612367uwaovjUD	All production
077.0752	Tubing holder right side	I	1	42446	A0680	07612367uwaovjUD	All production
Trolleys							
077.0188	Trolley A for DCS	I	1	42446	A0680	07612367uwaovjUD	All production
077.0190	Trolley B for DCS	I	1	42446	A0680	07612367uwaovjUD	All production
077.0511	Trolley small	I	1	42446	A0680	07612367uwaovjUD	All production
Quiver							
077.0531	Quiver 280mm	I	1	42446	A0680	07612367uwaovjUD	All production
077.0532	Quiver 480mm	I	1	42446	A0680	07612367uwaovjUD	All production