

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 *Vario Accessories 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: *Vario Accessories*
Product Category: *Body Fluid- and Vacuum Aspirator Systems, Accessories*

Intended Purpose: The accessories Vario Holders and adapter are intended to be used together with the Vario pumps to specifically enable the Vario pumps to be used in accordance with their intended purposes. The Vario holders are intended to attach the Vario securely to different rails. The Vario adapter is intended to attach the disposable fluid management system on Vario

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.

Authorised Signatories:



Annette Brüls, CEO *



Bianca Hedari, Director Quality CH

* Thomas Ertl, COO in representation of Annette Brüls

This Declaration of Conformity is effective from: 2021-05-17

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Article No.	Description	Class	Classification Rule	GMDN	CND-EMDN	Basic UDI	Scope of Application
077.0821	Vario rail holder 10x25 mm	I	1	43621	Z12019080	07612367ulhwydTA	all production
077.0822	Vario rail holder 10X30 mm	I	1	43621	Z12019080	07612367ulhwydTA	all production
077.0823	Vario Universal holder	I	1	43621	Z12019080	07612367ulhwydTA	all production
077.0825	Vario Rail holder	I	1	43621	Z12019080	07612367ulhwydTA	all production
077.0105	Adapter Vario (5 pcs)	I	1	43621	Z12019080	07612367ulhwydTA	all production