

**EC AND MANUFACTURER'S DECLARATION OF CONFORMITY  
EG KONFORMITÄTSERKLÄRUNG  
CE DÉCLARATION DE CONFORMITÉ  
CE DICHIARAZIONE DI CONFORMITÀ**

**Manufacturer's Name:** Medela AG

**Business Address:** Lättichstrasse 4b, (formerly 6341 Baar) 6340 Baar, Switzerland

**Medical Device(s):** Vario, Body Fluid - and Vacuum Aspirator Systems, see attached List

We declare under our sole responsibility, that the medical devices of **Class IIa** – see attached List, to which this declaration relates are in conformity with the provisions of the Council Directive 93/42/EEC (2007/47/EC). The medical devices are in conformity with the essential requirements of Annex I of the EEC directive. The conformity assessment procedure was performed according to Annex II excluding (4) of the EEC directive.

Wir erklären in alleiniger Verantwortung, dass die Medizinprodukte der Klasse IIa – gemäss Anhang, auf die sich diese Erklärung bezieht, übereinstimmen mit den Bestimmungen der Richtlinie des Rates 93/42/EWG (2007/47/EG). Die Medizinprodukte sind konform mit den grundlegenden Anforderungen gemäss Anhang I der Richtlinie. Das Konformitätsbewertungsverfahren wurde durchgeführt gemäss Anhang II der Richtlinie ohne Abschnitt (4).

Nous déclarons sous notre seule responsabilité que les dispositifs médicaux de la Classe IIa – conformément au document ci-joint, auxquels se réfère cette déclaration sont conforme avec les dispositions de la Directive du Conseil 93/42/CEE (2007/47/CE). Les dispositifs médicaux sont conforme aux exigences essentielles de l'annexe I de la directive. La procédure d'évaluation de la conformité a été effectuée conformément à l'annexe II de la directive, à l'exclusion du point (4).

Noi dichiariamo sotto la nostra sola responsabilità che i dispositivi medici della Classe IIa – secondo il documento allegato, ai quali questa dichiarazione si riferisce, sono in conformità alle disposizioni della Direttiva del Consiglio 93/42/CEE (2007/47/CE). I dispositivi medici soddisfano i requisiti essenziali dell'allegato I della direttiva. La procedura di valutazione di conformità è stata effettuata in accordo all'allegato II con esclusione del punto (4) II della direttiva.

**Full Quality Assurance System Certificate:**

European Medical Devices Directive MDD 93/42/EEC Annex II excluding (4)

TÜV Süd Cert. No.: G1 011634 0195



Notified Body id no. 0123

TÜV Süd Product Service GmbH, Ridlerstrasse 65, 80339 München, Germany

Applied harmonized standards are listed in the Essential Requirements Checklist of the medical devices.

**This Declaration of Conformity is valid until: 2024-05-25**

**Authorised Signatories:**



Annette Bruels, CEO \*

Baar/ Switzerland



Bianca Hedari, Director Quality CH

Baar/ Switzerland

This Declaration of Conformity is effective from: 2021-MAY-12

*\*Thomas Ertl, COO in representation of Annette Bruels.*

Mit dieser Ausgabe werden alle früheren Versionen ungültig

With this edition, all former versions become invalid

Avec cette édition, toutes les versions précédentes ne sont plus valables

Con questa edizione, tutte le versioni precedenti diventano non valide

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Article No.	Description	Class	Classification Rule	GMDN	Scope of Application
026.2110	Vario 18 AC	Ila	11	63642	all production
026.2112	Vario 18 AC	Ila	11	63642	all production
026.2120	Vario 18 AC	Ila	11	63642	all production
026.2140	Vario 18 AC	Ila	11	63642	all production
026.2150	Vario 18 AC	Ila	11	63642	all production
026.2160	Vario 18 AC	Ila	11	63642	all production
026.5110	Vario 18 AC/DC	Ila	11	63642	all production
026.5112	Vario 18 AC/DC	Ila	11	63642	all production
026.5120	Vario 18 AC/DC	Ila	11	63642	all production
026.5140	Vario 18 AC/DC	Ila	11	63642	all production
026.5150	Vario 18 AC/DC	Ila	11	63642	all production
026.7110	Vario 8 AC	Ila	11	63642	all production
026.7112	Vario 8 AC	Ila	11	63642	all production
026.7140	Vario 8 AC	Ila	11	63642	all production
026.7150	Vario 8 AC	Ila	11	63642	all production
026.7160	Vario 8 AC	Ila	11	63642	all production
026.8110	Vario 8 AC/DC	Ila	11	63642	all production
026.8111	Vario 8 c/i AC/DC	Ila	11	63642	all production
026.8112	Vario 8 AC/DC	Ila	11	63642	all production
026.8113	Vario 18 c/l AC/DC	Ila	11	63642	all production
026.8120	Vario 8 AC/DC	Ila	11	63642	all production
026.8122	Vario 18 c/i AC/DC	Ila	11	63642	all production
026.8123	Vario 8 c/i AC/DC	Ila	11	63642	all production
026.8140	Vario 8 AC/DC	Ila	11	63642	all production
026.8141	Vario c/i 8 AC/DC	Ila	11	63642	all production
026.8142	Vario 18 c/i AC/DC	Ila	11	63642	all production
026.8150	Vario 8 AC/DC	Ila	11	63642	all production
026.8151	Vario c/i 8 AC/DC	Ila	11	63642	all production
026.8152	Vario 18 c/i AC/DC	Ila	11	63642	all production
026.9001	Vario 18 AC	Ila	11	63642	all production