

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): Basic & Dominant Flex and KV-6/ Body Fluid-and Vacuum Aspirator Systems, see attached

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 Brüls, 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 Brüls.*

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
071.0001	Basic rack	Ila	11	63642	all production
071.0000	Basic portable	Ila	11	63642	all production
071.0003	Dominant Flex rack	Ila	11	63642	all production
071.0002*	Dominant Flex portable	Ila	11	63642	all production
071.0005	Olympus KV-6 Suction Pump	Ila	11	63642	all production
071.0036	IKRK Set Basic, sales no. 071.0001, Ila with accessories	Ila	11	63642	all production

*Stryker Ordering Reference Numbers 1010xxxx are contained on the pump box label and refer to specific label, IFU and plug configurations. These article numbers contain the identical, unchanged pump as per 071.0002 and only refer to labelling and plug variable combinations (101032949, 101032992, 101032993, 101032994, 101032995, 101032996, 101032997, 101032998, 101032999, 101033000, 101033001, 101033003, 101032949).