

**EC AND MANUFACTURER'S DECLARATION OF CONFORMITY
EG KONFORMITÄTSERKLÄRUNG
CE DÉCLARATION DE CONFORMITÉ
EC GYÁRTÓI MEGFELELŐSÉGI NYILATKOZAT**

Manufacture's Name: Medela AG
Business Address: Lättichstrasse 4b, (formerly 6341 Baar) 6340 Baar, Switzerland
Medical Device(s): Reuseble VAD Accessories, 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.

Note for Australia only: This is a declaration made in accordance with the requirements of Clause 1.8 of Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002 relating to the devices stated in the attached Schedule.

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 della 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).

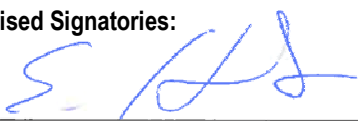
Kizárólagos felelősségünkre kijelentjük, hogy a IIa osztályú orvostechnikai eszközök - lásd a mellékelt listát - , amelyekre ez a nyilatkozat vonatkozik összhangban vannak a 93/42/EGK tanácsi irányelv (2007/47/EC) rendelkezéseivel. Az orvostechnikai eszközök megfelelnek az EGK irányelv I. mellékletének alapvető követelményeivel. A megfelelőség értékelési eljárást a II. mellékletnek megfelelően hajtották végre, kivéve az EGK-irányelv (4) bekezdését.

Full Quality Assurance System Certificate:
TÜV Süd Product Service GmbH, Notified Body id no. 0123
Ridlerstrasse 65, 80339 München, Germany
European Medical Devices Directive Annex II excluding (4)

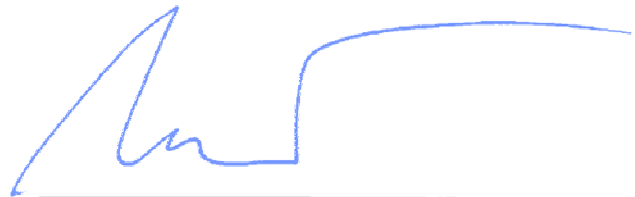
Applied harmonized standards are listed in the Essential Requirements Checklist of the medical devices.

This declaration of conformity is valid until: 2022-05-13

Authorised Signatories:



Erhard Hüsler, Director Quality CH



Leonhard Bauer, Executive Vice President Business Unit Healthcare

Baar/Switzerland: 2019-05-14

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Article No.	Description	Class	Classification Rule	GMDN	Scope of Application
077.0078	Silc-Cup, complete, ø 60 mm, with trumpet valve and 1.5 m silicone tubing	Ila	5	32596	all production
077.0761	Silc-Cup, ø 50mm with tubing and Coupling piece	Ila	5	32596	all production
077.0762	Silc-Cup, ø 60mm with tubing and Coupling piece	Ila	5	32596	all production
077.0080	CaesAid Cup, ø 60mm, with 2m silicone tubing	Ila	5	32596	all production
077.0063	Bird Posterior Cup ø 50mm with bottom plate, traction chain	Ila	5	32596	all production
077.0171	Bird Anterior Cup ø 60mm, compl. with handle and silicone tubing 150 cm	Ila	5	32596	all production
077.0172	Bird Anterior Cup ø 50mm, compl. with handle and silicone tubing 150 cm	Ila	5	32596	all production
077.0173	Bird Anterior Cup ø 40mm, compl. with handle and silicone tubing 150 cm	Ila	5	32596	all production
077.0174	Bird Posterior Cup ø 50mm, compl. with handle and silicone tubing 150 cm	Ila	5	32596	all production
077.0763	Bird Cup Set stainless steel ø 40mm, 50mm, 60mm	Ila	5	32596	all production
077.1041	Bird Anterior suction cup, ø 40 mm with plate and chain	Ila	5	32596	all production
077.0763	Bird Anterior suction cup, ø 50 mm with plate and chain	Ila	5	32596	all production
077.1043	Bird Anterior suction cup, ø 60 mm with plate and chain	Ila	5	32596	all production
077.0029	Malmström Cup ø 40mm, with bottom plate, chain, traction handle, tubing	Ila	5	32596	all production
077.0030	Malmström Cup ø 50mm, with bottom plate, chain, traction handle, tubing	Ila	5	32596	all production
077.0031	Malmström Cup ø 60mm, with bottom plate, chain, traction handle, tubing	Ila	5	32596	all production
077.0175	Malmström Cup ø 60mm, compl. with handle and silicone tubing 120cm	Ila	5	32596	all production
077.0176	Malmström Cup ø 50mm, compl. with handle and silicone tubing 120cm	Ila	5	32596	all production
077.0177	Malmström Cup ø 40mm, compl. with handle and silicone tubing 120cm	Ila	5	32596	all production