

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

**Manufacturer's Name:** Medela AG

**Business Address:** Lättichstrasse 4b, 6341 Baar, Switzerland

**Medical Device(s):** Symphony Pump Sets Reusable / Breastpumpsystem, see attached List

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).

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.

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, è 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:

TÜV Süd Product Service GmbH, Notified Body id no. 0123

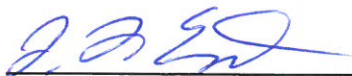
Ridlerstrasse 65, 80339 München, Germany

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:** 2021-05-16

**Authorised Signatories:**



Fritz Ender  
Director Quality CH



Annette Brüls  
CEO

Baar/Switzerland: 2018-05-17

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<b>Article No.</b>	<b>Description</b>	<b>Class</b>	<b>Classification Rule</b>	<b>GMDN</b>	<b>Scope of Application</b>
800.0566	Symphony Single Pump Set	Ila	2	61734	all production
800.0568	Symphony Single Pump Set	Ila	2	61734	all production
800.0570	Symphony Single Pump Set	Ila	2	61734	all production
200.1899	Symphony Single Pump Set	Ila	2	61734	all production
800.0653	Symphony Single Pump Set	Ila	2	61734	all production
200.5206	Symphony Single Pump Set	Ila	2	61734	all production
800.0560	Symphony Double Pump Set	Ila	2	61734	all production
800.0562	Symphony Double Pump Set	Ila	2	61734	all production
800.0564	Symphony Double Pump Set	Ila	2	61734	all production
200.1900	Symphony Double Pump Set	Ila	2	61734	all production
800.0654	Symphony Double Pump Set	Ila	2	61734	all production
008.0295	Symphony Double Pump Set incl. Calma	Ila	2	61734	all production
800.0557	Hospital Multibox M	Ila	2	61734	all production
200.1141	Hospital Multibox L	Ila	2	61734	all production
200.1143	Hospital Multibox XL	Ila	2	61734	all production
200.0029	Symphony Double Pump Set Special CH	Ila	2	61734	all production
200.0030	Symphony Double Pump Set Special CH	Ila	2	61734	all production