

**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): Symphony / Breastpumpsystem, 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 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: 2022-01-29

Authorised Signatories:



Erhard Hüsler
Director Quality CH



Annette Brüls
CEO

Baar/Switzerland: 2019-01-30

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Article No.	Description	Class	Classification		GMDN	Scope of Application
			Rule			
024.0000	Symphony	Ila	11		38478	all production
024.0001	Symphony	Ila	11		38478	all production
024.0002	Symphony	Ila	11		38478	all production
024.0003	Symphony	Ila	11		38478	all production
024.0004	Symphony	Ila	11		38478	all production
024.0005	Symphony	Ila	11		38478	all production
024.0006	Symphony	Ila	11		38478	all production
024.0007	Symphony	Ila	11		38478	all production
024.0008	Symphony	Ila	11		38478	all production
024.0009	Symphony	Ila	11		38478	all production
024.0010	Symphony	Ila	11		38478	all production
024.0011	Symphony	Ila	11		38478	all production
024.0012	Symphony	Ila	11		38478	all production
024.0101	Symphony	Ila	11		38478	all production
024.0102	Symphony	Ila	11		38478	all production
024.0103	Symphony	Ila	11		38478	all production
024.0104	Symphony	Ila	11		38478	all production
024.0105	Symphony	Ila	11		38478	all production
024.0106	Symphony	Ila	11		38478	all production
024.0107	Symphony	Ila	11		38478	all production
024.0108	Symphony	Ila	11		38478	all production
024.0109	Symphony	Ila	11		38478	all production
024.0201	Symphony	Ila	11		38478	all production
024.0202	Symphony	Ila	11		38478	all production
024.0203	Symphony	Ila	11		38478	all production
024.0204	Symphony	Ila	11		38478	all production
024.0205	Symphony	Ila	11		38478	all production
024.0206	Symphony	Ila	11		38478	all production
024.0207	Symphony	Ila	11		38478	all production
024.0209	Symphony	Ila	11		38478	all production
024.0301	Symphony	Ila	11		38478	all production
024.0302	Symphony	Ila	11		38478	all production
024.0303	Symphony	Ila	11		38478	all production
024.0304	Symphony	Ila	11		38478	all production
024.0305	Symphony	Ila	11		38478	all production
024.0307	Symphony	Ila	11		38478	all production
024.0308	Symphony	Ila	11		38478	all production
024.0309	Symphony	Ila	11		38478	all production
024.0310	Symphony	Ila	11		38478	all production
024.0311	Symphony	Ila	11		38478	all production
024.0401	Symphony	Ila	11		38478	all production
024.0402	Symphony	Ila	11		38478	all production
024.0403	Symphony	Ila	11		38478	all production
024.0404	Symphony	Ila	11		38478	all production
024.0405	Symphony	Ila	11		38478	all production