

**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 Program Cards, 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.

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 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.

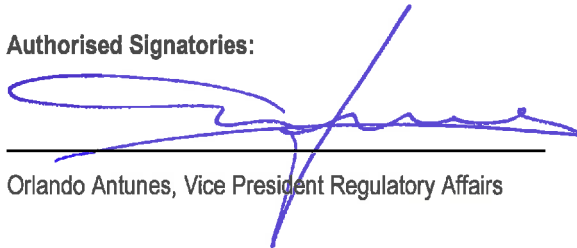
Noi dichiariamo sotto la nostra sola responsabilità che i dispositivi medici della Classe IIa – secondo il documento allegato, ai quali questa dichiarazione si riferisce, è in conformità alle disposizioni della Direttiva del Consiglio 93/42/CEE (2007/47/CE). I dispositivi medici soddisfano i requisiti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

Full Quality Assurance System Certificate:
TÜV Süd Product Service GmbH, Notified Body id no. 0123
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: 2018-11-23

Authorised Signatories:


Orlando Antunes, Vice President Regulatory Affairs
Patrik Bosshard, Vice President Operations

Baar/Switzerland: 2015-11-24

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Article No.	Description	Class	Classification Rule	GMDN	Scope of Application
200.9186	Symphony PLUS Program Card, EN	Ila	11	38478	all production
200.9187	Symphony PLUS Program Card, DE	Ila	11	38478	all production
200.9188	Symphony PLUS Program Card, FR	Ila	11	38478	all production
200.9189	Symphony PLUS Program Card, NL	Ila	11	38478	all production
200.9190	Symphony PLUS Program Card, ES	Ila	11	38478	all production
200.9191	Symphony PLUS Program Card, IT	Ila	11	38478	all production
200.9192	Symphony PLUS Program Card, PT	Ila	11	38478	all production
200.9193	Symphony PLUS Program Card, SV	Ila	11	38478	all production
200.9194	Symphony PLUS Program Card, NO	Ila	11	38478	all production
200.9195	Symphony PLUS Program Card, DA	Ila	11	38478	all production
200.9196	Symphony PLUS Program Card, FI	Ila	11	38478	all production
200.9197	Symphony PLUS Program Card, PL	Ila	11	38478	all production
200.9198	Symphony PLUS Program Card, JA	Ila	11	38478	all production
200.9200	Symphony PLUS Program Card, USA	Ila	11	38478	all production
800.0541	Symphony Standard Program Card, EN	Ila	11	38478	all production
800.0540	Symphony Standard Program Card, DE	Ila	11	38478	all production
800.0542	Symphony Standard Program Card, FR	Ila	11	38478	all production
800.0543	Symphony Standard Program Card, IT	Ila	11	38478	all production
800.0544	Symphony Standard Program Card, NL	Ila	11	38478	all production
800.0545	Symphony Standard Program Card, SV	Ila	11	38478	all production
800.0546	Symphony Standard Program Card, DA	Ila	11	38478	all production
800.0547	Symphony Standard Program Card, FI	Ila	11	38478	all production
800.0578	Symphony Standard Program Card, NO	Ila	11	38478	all production
800.0549	Symphony Standard Program Card, PL	Ila	11	38478	all production
800.0550	Symphony Standard Program Card, ES	Ila	11	38478	all production
800.0551	Symphony Standard Program Card, PT	Ila	11	38478	all production
800.0552	Symphony Standard Program Card, EL	Ila	11	38478	all production
800.0553	Symphony Standard Program Card, HU	Ila	11	38478	all production
800.0554	Symphony Standard Program Card, CS	Ila	11	38478	all production