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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): Hydrogel Pads/ Breastfeeding Product, 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: 2021-07-22

Authorised Signatories:

Annette Brüls, CEO

Fritz Ender, Director Quality CH a.i.

Baar/Switzerland: 2018-07-23

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Article No.	Description	Class	Classification Rule	GMDN	Scope of Application
008.0052	Hydrogel Pads	IIa	4	61948	all production
008.0053	Hydrogel Pads	IIa	4	61948	all production
008.0054	Hydrogel Pads	IIa	4	61948	all production
008.0055	Hydrogel Pads	IIa	4	61948	all production
008.0056	Hydrogel Pads	IIa	4	61948	all production
008.0163	Hydrogel Pads	IIa	4	61948	all production
008.0057	Hydrogel Pads	IIa	4	61948	all production
008.0058	Hydrogel Pads	IIa	4	61948	all production
008.0059	Hydrogel Pads	IIa	4	61948	all production
008.0060	Hydrogel Pads	IIa	4	61948	all production
008.0061	Hydrogel Pads	IIa	4	61948	all production
008.0062	Hydrogel Pads	IIa	4	61948	all production
008.0164	Hydrogel Pads	IIa	4	61948	all production