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EC AND MANUFACTURER'S DECLARATION OF CONFORMITY
EG KONFORMITÄTSERKLÄRUNG
CE DÉCLARATION DE CONFORMITÉ
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Manufacturer's Name: Medela AG

Business Address: Lättichstrasse 4b, (formerly 6341 Baar) 6340 Baar, Switzerland

Medical Device(s): Clario Toni/ Body Fluid-and Vacuum Aspirator Systems, 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.

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, sono 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:

European Medical Devices Directive MDD 93/42/EEC Annex II excluding (4)

TÜV Süd Cert. No.: TÜV Süd Cert. No.: G1 011634 0195

Notified Body id no. 0123

TÜV Süd Product Service GmbH, Ridlerstrasse 65, 80339 München, Germany

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

This Declaration of Conformity is valid until: 2024-05-25

Authorised Signatories:

Name, Annette Bruels, CEO

Baar/ Switzerland

Name, Bianca Hedari, Director Quality CH

Baar/ Switzerland

This Declaration of Conformity is effective from: 2021-01-13

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Article No.	Description	Class	Classification Rule	GMDN	Scope of Application
014.0022	Clario Toni Home Care Pump AC/DC Version	IIa	11	36777	all production
014.0023	Clario Toni Home Care Pump AC/DC Version	IIa	11	36777	all production
014.0024	Clario Toni Home Care Pump AC/DC Version	IIa	11	36777	all production
014.0025	Clario Toni Home Care Pump AC/DC Version	IIa	11	36777	all production
014.0026	Clario Toni Home Care Pump Deluxe Version	IIa	11	36777	all production
014.0027	Clario Toni Home Care Pump Deluxe Version	IIa	11	36777	all production
014.0028	Clario Toni Home Care Pump Deluxe Version	IIa	11	36777	all production
014.0029	Clario Toni Home Care Pump Deluxe Version	IIa	11	36777	all production
014.0031	Clario Toni Home Care Pump Deluxe Version	IIa	11	36777	all production
014.0032	Clario Toni Home Care Pump AC/DC Version	IIa	11	36777	all production