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# 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):** Sterile Tubing, see attached List

We declare under our sole responsibility, that the medical devices of **Class Is** – 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 V of the EEC directive.

Wir erklären in alleiniger Verantwortung, dass die Medizinprodukte der Klasse Is – 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 V der Richtlinie.

Nous déclarons sous notre seule responsabilité que les dispositifs médicaux de la Classe Is – 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 V de la directive.

Noi dichiariamo sotto la nostra sola responsabilità che i dispositivi medici della Classe Is – 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 V della direttiva.

**Production Quality Assurance Certificate:**

European Medical Devices Directive MDD 93/42 EEC Annex V

TÜV Süd Cert. No.: G2S 011634 0169

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:**

Annette Brüls, CEO
Baar/ Switzerland

Bianca Hedari, Director Quality CH
Baar/ Switzerland

This Declaration of Conformity is effective from: 2020-11-18

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| Article No. | Description | Class | Classification Rule | GMDN | Scope of Application |
|---|---|---|---|---|---|
| 620.0018 | Disposable tubing with two funnels, 300 cm, CH30, sterile | Is | 1 | 16779 | all production |
| 077.0170 | Disposable PVC tubing, 150 cm | Is | 1 | 16779 | all production |
| 077.0184 | Disposable tubing PVC, 150 cm, CH25, with two connect-ors | Is | 1 | 16779 | all production |
| 077.0951 | Disposable PVC tubing,180 cm, CH25, with fingertip | Is | 1 | 16779 | all production |
| 080.0051 (K3920733) | Tubing 2M Single | Is | 1 | 16779 | all production |
| 077.0193 | AXS Universal™ Aspiration Tubing | Is | 1 | 16779 | all production |