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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, (formerly 6341 Baar) 6340 Baar, Switzerland

**Medical Device(s):** Tubing-Filters-Coupling pieces / Body Fluid and Vacuum Aspirator Systems, see attached List

We declare under our sole responsibility, that the medical devices of Class I – 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 VII of the EEC directive.

Note for Australia only: This is a declaration made in accordance with the requirements of Clause 6.6 of Schedule 3 of the Australian Therapeutic Goods (Medical Devices) Regulations 2002 relating to the devices stated in the attached List.

Wir erklären in alleiniger Verantwortung, dass die Medizinprodukte der Klasse I – 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 VII der Richtlinie.

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

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

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

**This declaration of conformity is valid until:** 2022-06-23

**Authorised Signatories:**

Erhard Huesler, Director Quality CH

Annette Bruels, CEO

Baar/Switzerland: 2019-06-24

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| Article No | Description | Class | Classification Rule | GMDN | Scope of Application |
|---|---|---|---|---|---|
| ***Tubing*** | | | | | |
| 077.0095 | Serial connection, y-piece with 25cm silicone tubing | I | 1 | 16779 | all production |
| K10021188 | Y piece serial connection vacuum | I | 1 | 16779 | all production |
| 077.0154 | Serial connection, 25cm silicone tubing with one coupling piece to connect to pump | I | 1 | 16779 | all production |
| K10021878 | Serial Connection Vacuum & 1 Coupling Piece | I | 1 | 16779 | all production |
| 077.0158 | Serial connection, Serial connectors with 34 cm PVC tubing (100 pcs) | I | 1 | 16779 | all production |
| K10021885 | Serial Connection Patient (100 pcs) | I | 1 | 16779 | all production |
| 077.0160 | Serial connection, Serial connector with 34cm PVC tubing (1 pc) | I | 1 | 16779 | all production |
| 077.0970 | Silicone tubing Ø 5x 10mm, 25m | I | 1 | 16779 | all production |
| 077.0900 | Silicone tubing Ø 7x 12mm, without coupling pieces, 25m | I | 1 | 16779 | all production |
| 077.0901 | Silicone tubing Ø 7x 12mm, without coupling pieces, 1m | I | 1 | 16779 | all production |
| 077.0902 | Silicone tubing Ø 7x 12mm, without coupling pieces, 2m | I | 1 | 16779 | all production |
| 077.0905 | Silicone tubing Ø 7x 12mm, without coupling pieces, 5m | I | 1 | 16779 | all production |
| 077.0911 | Silicone tubing Ø 7x 12mm, with one coupling piece, 33 cm | I | 1 | 16779 | all production |
| 077.0912 | Silicone tubing Ø 7x 12mm, with one coupling piece, 60cm | I | 1 | 16779 | all production |
| 077.0913 | Silicone tubing Ø 7x 12mm, with one coupling piece, 100cm | I | 1 | 16779 | all production |
| 077.0921 | Silicone tubing Ø 7x 12mm, with two coupling pieces, 30cm | I | 1 | 16779 | all production |
| 077.0922 | Silicone tubing Ø 7x 12mm, with two coupling pieces, 60cm | I | 1 | 16779 | all production |
| K10026804 | KV-6 Connection Tube ID 7mm x 60cm long – straight ends | I | 1 | 16779 | all production |
| 077.0931 | Silicone tubing Ø 7x 12mm, with two coupling pieces, 25cm | I | 1 | 16779 | all production |
| 077.0185 | Silicone tubing Ø 7.0 X 12.0 mm, 60cm with two coupling pieces | I | 1 | 16779 | all production |
| K10026130 | KV-6 Connection Tube ID 7mm x 60cm long | I | 1 | 16779 | all production |
| 077.0961 | Silicone tubing green Ø 6.5x12.5mm, 180cm with coupling piece | I | 1 | 16779 | all production |
| 077.0963 | PVC tubing Ø 12.7x 18mm, 180cm with coupling piece | I | 1 | 16779 | all production |
| 077.0156 | Vacuum tubing for serial connection of 4 suction liners | I | 1 | 16779 | all production |
| 077.0157 | Patient tubing for serial connection of 4 suction liners | I | 1 | 16779 | all production |
| 077.0189 | Silicone tubing D 7X12mm, | I | 1 | 16779 | all production |

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| | | | | | |
|---|---|---|---|---|---|
| | 300cm with 2 coupling pieces | | | | |
| ***Filters*** | | | | | |
| 077.0571 | Disposable overflow protection / bacteria filter | I | 1 | 37798 | all production |
| K10026028 | Disposable overflow protection / bacteria filter for KV-6 | I | 1 | 37798 | all production |
| 077.0572 | Disposable overflow protection / bacteria filter with conical connections | I | 1 | 37798 | all production |
| 077.0573 | Disposable bacteria filter with Medela connections | I | 1 | 37798 | all production |
| K10027322 | KV-6 Bacteria Filter | I | 1 | 37798 | all production |
| 077.0574 | Disposable bacteria filter with conical connections | I | 1 | 37798 | all production |
| 077.0575 | Disposable bacteria /odour filter with Medela connection | I | 1 | 37798 | all production |
| K10027321 | KV-6 Odour/Bacteria Filter | I | 1 | 37798 | all production |
| 077.0576 | Disposable bacteria /odour filter with conical connection | I | 1 | 37798 | all production |
| 077.0582 | Disposable particle filter with Medela conncetions | I | 1 | 37798 | all production |
| 077.0092 | Disposable overflow protection / bacteria / odour filter with Medela connections, 10 pcs | I | 1 | 37798 | all production |
| K10026126 | Disposable overflow protection / bacteria / odour filter for KV-6 | I | 1 | 37798 | all production |
| 077.0581 | Bacteria filter autoclavable | I | 1 | 37798 | all production |
| 077.0577 | Disposable overflow protection / bacteria filter with conical and Medela connections | I | 1 | 37798 | all production |
| 077.0834 | Vario disposable filter set with overflow/bacteria filter | I | 1 | 37798 | all production |
| 077.1014 | Filter paper for autoclavable bacteria filter | I | 1 | 37798 | all production |
| 101035263 | Disposable OverflowProtection/Virus filter, Medela connection, 10pcs | I | 1 | 37798 | all production |
| 101035264 | Disposable Overflow Protection/Virus filter, conical connections, 10pcs | I | 1 | 37798 | all production |
| 101035265 | Disposable virus filter with Medela connections Set of 10 pcs | I | 1 | 37798 | all production |
| 101035284 | Disposable virus filter with conical connection Set of 10 pcs | I | 1 | 37798 | all production |
| 101035285 | Disposable Overflow Protection/Bacteria Odour Filter with Medela connections, 10 pcs | I | 1 | 37798 | all production |
| 101035286 | Disposable Overflow Protection/Virus Odour Filter with Medela connections, 10 pcs | I | 1 | 37798 | all production |
| 101035287 | Disposable Overflow Protection/Virus Odour Filter with conical connections, 10pcs | I | 1 | 37798 | all production |
| 101035288 | Disposable virus/ odour filter with Medela connections. Set of 10 pcs | I | 1 | 37798 | all production |
| 101035289 | Disposable virus/odour filter with conical connection. Set of 10 pcs | I | 1 | 37798 | all production |
| ***Coupling pieces*** | | | | | |
| 077.0097 | Y-piece Ø 7 mm / 5mm | I | 1 | 16779 | all production |

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| | | | | | |
|---|---|---|---|---|---|
| 077.0098 | Y-piece Ø 7 mm | I | 1 | 16779 | all production |
| 077.1018 | Coupling piece | I | 1 | 16779 | all production |
| 077.1019 | Coupling piece 90° | I | 1 | 16779 | all production |
| 077.1017 | Double conical coupling piece | I | 1 | 16779 | all production |
| 077.1020 | Y-Piece | I | 1 | 16779 | all production |
| 077.1015 | Angle piece Ø 6-10mm | I | 1 | 16779 | all production |
| 077.1016 | Angle piece Ø 10-14mm | I | 1 | 16779 | all production |
| 077.0542 | Reusable serial connector | I | 1 | 16779 | all production |
| 077.1011 | Coupling piece | I | 1 | 16779 | all production |
| 077.1012 | Coupling piece 90° | I | 1 | 16779 | all production |
| 077.1021 | Overflow protection device Set of 10 pcs | I | 1 | 16779 | all production |
| 077.1022 | Drainage valve | I | 1 | 16779 | all production |
| 077.1023 | Plug for FMS lids, set of 10 pcs | I | 1 | 16779 | all production |
| 077.0161 | Coupling piece 5 mm - set of 10 pcs | I | 1 | 16779 | all production |
| 077.0163 | Trolley short one rail | I | 1 | 16779 | all production |