

**EG KONFORMITÄTSERKLÄRUNG
EC DECLARATION AND MANUFACTURER'S DECLARATION OF CONFORMITY
CE DÉCLARATION DE CONFORMITÉ
CE DICHIARAZIONE DI CONFORMITÀ
Full quality assurance procedure**

Manufacturer's Name: Medela AG
Business Address: Lättichstrasse 4b, PO Box 353, 6341 Baar, Switzerland
Medical Device(s): General Aspirator Accessories - See attached Schedule
Classification: Class I, IIa - See attached Schedule

GMDN Code and Term:

[16779] Suction system tubing	[37798] Suction system filter, microbial
[17115] Battery charger	[38476] Suction system bottle
[20395] Suction system, wound, powered	[42446] Suction system canister/bottle holder
[34858] Suction system canister, single-use	[43324] Fluid transfer set, general-purpose
[36777] Suction system, general-purpose, line-powered	[44942] Suction system canister liner
[36787] Gauge as part of Thoracic Suction system	[44943] Suction system canister, reusable
[37040] Anaesthesia breathing tube holder	[46215] Drainage system fluid collector, pleural
[37075] Mount, general-purpose	- See Attached Schedule

Scope of Application: - See Attached Schedule

Wir erklären in alleiniger Verantwortung, dass die Medizinprodukte der Klasse I, IIa oder IIb – 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 Anforderung gemäss Anhang I der Richtlinie. Das Konformitätsbewertungsverfahren wurde durchgeführt gemäss Anhang II (Klasse IIa/IIb) oder VII (Klasse I) der Richtlinie.

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.

We declare under our sole responsibility, that the medical devices of class I, IIa or IIb – see attached Schedule, to which this declaration relates are in conformity with the provisions of the Council Directive 93/42/EEC (2007/47/EC). Each kind of medical device to which the Full Quality Assurance Procedures have been applied complies with the applicable provisions of the essential principles, the classification rules, at each stage, from the design of the device until its final inspection before being supplied. 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 (class IIa/IIb) or VII (class I) of the EEC directive.

Nous déclarons sous notre seule responsabilité que les dispositifs médicaux de la classe I, IIa ou IIb – 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 (classe IIa/IIb) ou VII (classe I) de la directive.

Noi dichiariamo sotto la nostra sola responsabilità che i dispositivi medici della classe I, IIa o IIb – 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 (classe IIa/IIb) o VII (classe I) della direttiva.

Full Quality Management System Certificate:

TÜV Süd Product Service GmbH, No. G1 08 10 11634 090, Notified Body id no. 0123:
European Medical Devices Directive Annex II, Section 3, without Clause 4 Certificate (class IIa/IIb devices only)

Standards Applied: ISO 13485
IEC 60601-1 IEC 60601-1-2 IEC 60601-1-4 IEC 60601-1-6
ISO 10079-1 ISO 10993 series ISO 19054 EN 550

Notes: These standards do not necessarily apply to all parts of the product group in attached Schedule.
The editions of above standards correspond with the harmonized standards, of which the reference numbers have been published in the Official Journal of the European Union.

Authorised Signatories:



Markus Büttler, Vice President - Quality Mgmt & Regulatory Affairs



Marcel Felber, President

Date: August 05, 2010

Reference Article No.	Description	Class	Effectivity	
			GMDN	point
077.0521	Holders and Clampholders	I	42446	all production
077.0525	Holders and Clampholders	I	42446	all production
077.0826	Holders and Clampholders	I	42446	all production
077.0827	Holders and Clampholders	I	42446	all production
077.1458	Holders and Clampholders	I	42446	all production
077.1471	Holders and Clampholders	I	42446	all production
079.0036	Holder with standard rail	I	42446	all production
077.0104	Clampholder CH	I	42446	all production
077.0152	Clamp holder for foreign jars	I	42446	all production
077.0651	Safety device	Ila	38476	all production
077.0711	Safety device	Ila	38476	all production
077.0712	Safety device	Ila	38476	all production
077.0110	Suction jar, polysulfone	Ila	38476	all production
077.0120	Suction jar, polysulfone	Ila	38476	all production
077.0125	Suction jar, polysulfone	Ila	38476	all production
077.0130	Suction jar, polysulfone	Ila	38476	all production
077.0150	Suction jar, polysulfone	Ila	38476	all production
077.0155	Suction jar, polysulfone	Ila	38476	all production
077.0111	Thorax jar PSU 1 litre	Ila	46215	all production
077.0210	Suction jar, polycarbonate	Ila	44943	all production
077.0211	Suction jar, polycarbonate	Ila	44943	all production
077.0212	Suction jar, polycarbonate	Ila	44943	all production
077.0220	Suction jar, polycarbonate	Ila	44943	all production
077.0221	Suction jar, polycarbonate	Ila	44943	all production
077.0222	Suction jar, polycarbonate	Ila	44943	all production
077.0230	Suction jar, polycarbonate	Ila	44943	all production
077.0231	Suction jar, polycarbonate	Ila	44943	all production
077.0232	Suction jar, polycarbonate	Ila	44943	all production
077.0082	Suction jar, polycarbonate 1,5L, Flexibag	I	44943	all production
077.0085	Suction jar, polycarbonate 2,5L, Flexibag	I	44943	all production
077.0310	Disposable suction bag	I	44942	all production
077.0312	Disposable suction bag	I	44942	all production
077.0319	Disposable suction bag	I	44942	all production
077.0320	Disposable suction bag	I	44942	all production
077.0322	Disposable suction bag	I	44942	all production
077.0329	Disposable suction bag	I	44942	all production
077.0330	Disposable suction bag	I	44942	all production
077.0332	Disposable suction bag	I	44942	all production
077.0339	Disposable suction bag	I	44942	all production
077.0083	Disposable suction bag 1,5L, Flexibag	I	44942	all production
077.0086	Disposable suction bag 2,5L, Flexibag	I	44942	all production
077.0311	Disposable Suction Bag with Solidifier	I	44942	all production
077.0313	Disposable Suction Bag with Solidifier	I	44942	all production
077.0321	Disposable Suction Bag with Solidifier	I	44942	all production
077.0323	Disposable Suction Bag with Solidifier	I	44942	all production
077.0324	Disposable Suction Bag with Solidifier	I	44942	all production
077.0331	Disposable Suction Bag with Solidifier	I	44942	all production
077.0333	Disposable Suction Bag with Solidifier	I	44942	all production
077.0084	Disposable Suction Bag with Solidifier 1,5L, Flexibag	I	44942	all production
077.0087	Disposable Suction Bag with Solidifier 2,5L, Flexibag	I	44942	all production
077.0420	Large lid with conical patient connection	I	38476	all production
077.0421	Large lid with conical patient connection	I	38476	all production
077.0430	Large lid with conical patient connection	I	38476	all production
077.0410	Lid for disposable suction bag	I	38476	all production
077.0411	Thorax lid 1 litre	Ila	38476	all production
077.0440	Small lid with conical patient connection	I	38476	all production
077.0441	Small lid with conical patient connection	I	38476	all production
077.0450	Lid for safety jar	I	38476	all production
077.0511	Trolley	I	37075	all production
077.0163	Trolley small	I	37075	all production
620.0221	Trolley, stainless steel	I	37075	all production
600.0680	Trolley for Basic 30 and Dominant 50	I	37075	all production
600.0684	Trolley for Dominant 35ci	I	37075	all production
077.0523	Wall bracket	I	42446	all production
077.0524	Wall bracket	I	42446	all production
077.0542	Disposable / Reusable serial connector	I	36777	all production
077.0551	Drainage set	Ila	20395	all production

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077.0552	Drainage set	Ila	20395	all production
077.0553	Drainage set	Ila	20395	all production
077.0561	Change-over valve	I	36777	all production
077.0563	Change-over valve	I	36777	all production
077.0562	Disposable specimen cup	I	36777	all production
077.0564	Disposable specimen cup	I	36777	all production
077.0573	Disposable bacteria filter	I	37798	all production
077.0574	Disposable bacteria filter	I	37798	all production
077.0575	Disposable bacteria/odour filter	I	37798	all production
077.0576	Disposable bacteria/odour filter	I	37798	all production
077.0571	Disposable overflow protection/bacteria filter	I	37798	all production
077.0138	Disposable overflow protection/bacteria filter	I	37798	all production
600.0492	Filterset Vario with 5 disposable overflow protection/bacteria filter	I	37798	all production
080.0009	Disposable overflow protection/bacteria filter (20 pcs)	I	37798	all production
077.0572	Disposable overflow protection/bacteria filter	I	37798	all production
077.0577	Disposable overflow protection/bacteria filter	I	37798	all production
077.0581	Bacteria filter autoclavable	I	37798	all production
077.0582	Disposable particle filter	I	37798	all production
077.0701	Reusable set 1/2/3/5 liter	Ila	38476	all production
077.0702	Reusable set 1/2/3/5 liter	Ila	38476	all production
077.0703	Reusable set 1/2/3/5 liter	Ila	38476	all production
077.0704	Reusable set 1/2/3/5 liter	Ila	38476	all production
077.0705	Reusable set 1/2/3/5 liter	Ila	38476	all production
077.0706	Reusable set 1/2/3/5 liter	Ila	38476	all production
077.0707	Reusable set 1/2/3/5 liter	Ila	38476	all production
077.0715	Reusable set 1/2/3/5 liter	Ila	38476	all production
077.0716	Reusable set 1/2/3/5 liter	Ila	38476	all production
077.0721	Foot switch ON/OFF	I	36777	all production
077.0722	Foot switch ON/OFF	I	36777	all production
077.0723	Foot switch ON/OFF	I	36777	all production
077.0731	Foot vacuum regulator	I	36777	all production
077.0139	Low vacuum regulator direct	I	36777	all production
077.0751	Tubing holder	I	37040	all production
077.0108	Tubing holder	I	37040	all production
077.0752	Tubing holder	I	37040	all production
077.0109	Tubing holder	I	37040	all production
077.0811	Disposable set 1 I	Ila	34858	all production
077.0107	Vario rail holder	I	36777	all production
077.0821	Vario rail holder	I	36777	all production
077.0822	Vario rail holder	I	36777	all production
077.0823	Vario universal holder	I	36777	all production
077.0824	Vario trolley plate	I	36777	all production
077.0825	Vario holder fixed	I	36777	all production
077.0831	Vario carrying bag	I	36777	all production
077.0149	Mains cable for Basic 30 / Dominant 50 with equipotentiality cable 5m	I	47487	all production
077.0832	Car connection cable 12 VDC Vario	I	36777	all production
077.0113	Vario disposable filter set with overflow protection/bacteria filter	I	37798	all production
077.0834	Vario disposable filter set with overflow protection/bacteria filter	I	37798	all production
800.0849	Disp. overflow protection/bacteria filter Medela & conical connection	I	37798	all production
077.0092	Disp. overflow protection/bacteria/odor filter with Medela connection	I	37798	all production
077.0900	Silicon tubing with/without 1/2 coupling piece	I	16779	all production
077.0901	Silicon tubing with/without 1/2 coupling piece	I	16779	all production
077.0902	Silicon tubing with/without 1/2 coupling piece	I	16779	all production
077.0905	Silicon tubing with/without 1/2 coupling piece	I	16779	all production
077.0911	Silicon tubing 12x7, 33cm, with coupling piece	I	16779	all production
077.0912	Silicon tubing with/without 1/2 coupling piece	I	16779	all production
077.0913	Silicon tubing with/without 1/2 coupling piece	I	16779	all production
077.0921	Silicon tubing with/without 1/2 coupling piece	I	16779	all production
077.0922	Silicon tubing with/without 1/2 coupling piece	I	16779	all production
077.0931	Silicon tubing with/without 1/2 coupling piece	I	16779	all production
077.0961	Silicon tubing with/without 1/2 coupling piece	I	16779	all production
077.0970	Silicon tubing with/without 1/2 coupling piece	I	16779	all production
077.0962	Tubing	I	16779	all production
077.0963	Tubing 12x6,5 mm / 180 cm with coupling piece	I	16779	all production
077.0964	Tubing sterile 12x6,5 mm / 200 cm with coupling piece	I sterile	16779	all production
077.0154	Tubing 12x6,5 mm / 200 cm with coupling piece	I	16779	all production
077.0093	Tubing set for double drainage	I	16779	all production
077.0158	Tubing	I	16779	all production
077.1015	Angle piece	I	36777	all production

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077.1016	Angle piece	I	36777	all production
077.1020	Y-piece (10 pcs)	I	36777	all production
077.1011	Coupling / Coupling piece 90°	I	36777	all production
077.1012	Coupling / Coupling piece 90°	I	36777	all production
077.1018	Coupling / Coupling piece 90°	I	36777	all production
077.1019	Coupling / Coupling piece 90°	I	36777	all production
077.0161	Coupling / Coupling piece 5mm	I	36777	all production
077.1017	Conical Double Connector	I	36777	all production
077.1021	Overflow protection device	I	36777	all production
077.1022	Drainage valve	I	36777	all production
077.1023	Plug for FMS lids	I	36777	all production
077.1024	Disposable hydrofobic filter	I	37798	all production
077.1026	Bellow for drainage valve	I	36777	all production
077.1460	TDS Trolley with infusion holder	I	36777	all production
077.1461	TDS Trolley with infusion holder	I	36777	all production
077.1462	TDS Trolley with infusion holder	I	36777	all production
077.1463	TDS Trolley with infusion holder	I	36777	all production
080.0023	Suction jar, polysulfone	Ila	38476	all production
080.0024	Suction jar, polysulfone	Ila	38476	all production
080.0031	Olympus K7503427 Disposable suction bag	I	44942	all production
080.0032	Olympus K7503429 Disposable suction bag	I	44942	all production
080.0033	Olympus K7503428 Disposable Suction Bag with Solidifier	I	44942	all production
080.0034	Olympus K7503430 Disposable Suction Bag with Solidifier	I	44942	all production
080.0035	Olympus K7503431 Disposable Suction Bag with Solidifier	I	44942	all production
080.0041	Olympus K7503761 Lid for disposable suction bag	I	38476	all production
080.0042	Olympus K7503760 Large lid with conical patient connection	I	38476	all production
080.0201	Medtronics Kit 1	Ila	36777	all production
080.0202	Medtronics Kit 2	Ila	36777	all production
800.0106	Lid with Mech. Overflow Protection Device	Ila	38476	all production
800.0107	Lid with Overflow Sensor and Mech. Overflow Protection	Ila	38476	all production
800.0110	Disposable dust cover for suction pumps	I	36777	all production
811.0011	Suction Container Polysulfone	Ila	38476	all production
811.0014	Suction Container Polysulfone	Ila	38476	all production
077.0531	Holder for quiver / Quiver	I	36777	all production
077.0532	Holder for quiver / Quiver	I	36777	all production
077.1030	Holder for quiver / Quiver	I	36777	all production
077.1031	Holder for quiver / Quiver	I	36777	all production
077.1032	Holder for quiver / Quiver	I	36777	all production
077.1440	Disposable canister for thorax drainage, sterile	I sterile	34858	all production
077.1445	Disposable canister for thorax drainage, sterile	I sterile	34858	all production
077.1456	Gauge for disposable canister	I	36787	all production
079.0011	THOPAZ disposable canister 0.3l	I sterile	34858	all production
079.0012	THOPAZ disposable canister with solidifier 0.3l	I sterile	34858	all production
079.0016	THOPAZ disposable canister 0.8l	I sterile	34858	all production
079.0017	THOPAZ disposable canister with solidifier 0.8l	I sterile	34858	all production
079.0021	THOPAZ tubing set	I sterile	16779	all production
079.0022	THOPAZ tubing set double	I sterile	16779	all production
077.1412	Thorax Set 1 or 2 chamber system	Ila	34858	all production
077.1432	TDS Basic 1 or 2 chamber system	Ila	34858	all production
200.1733	Safety device set Vario ICRC	Ila	38476	all production
074.0017	Clario Car connection cable 12 VDC	I	36777	all production
074.0001	Clario Canister set	I	36777	all production
074.0002	Clario SafetyChamber	I	36777	all production
074.0004	Clario Set incl. SafetyChamber,canister and disposable fingertip tubing	I sterile	36777	all production
074.0007	Clario SoftCase	I	36777	all production
079.0031	Carrying Strap	I	36777	all production
077.0105	Adapter Vario	I	42446	all production
077.0094	Disposable specimen cup for disposable system	I	36777	all production
077.0095	Serial connection vacuum Disposable System	I	36777	all production
077.0096	Serial connection patient Disposable System	I	36777	all production
077.0160	Serial connection patient	I	36777	all production
077.0156	Vacuum tubing for serial connection of 4 suction liners	I	36777	all production
077.0157	Patient tubing for serial connection of 4 suction liners	I	36777	all production
077.0097	Y-piece 7/5 mm Disposable System	I	36777	all production
500.2192	Holder 10x25 for 1 liter suction jar	I	42446	all production
079.0032	Docking Station	I	17115	all production
079.0037	Docking Station	I	17115	all production
079.0039	Thopaz cap	I sterile	43324	all production