

**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):** Medical Aspirators - See attached Schedule  
**Classification:** Class IIa - See attached Schedule  
**GMDN Code and Term:** [36777] Suction system, general-purpose, line-powered  
[36778] Suction system, general-purpose, vacuum-powered  
[36787] Thoracic suction system  
[20395] Aspirators as part of Suction system, wound, powered  
[36894] Liposuction system  
- 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 Anforderungen 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 10079-2 ISO 10993 series ISO 19054

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 Bütler, Vice President - Quality Mgmt & Regulatory Affairs



Marcel Felber, President

Date: August 10, 2010

Reference Article No.	Description	Class	GMDN	Effectivity point
014.0010	Clario Home Care Pump AC Version	Ila	36777	all production
014.0011	Clario Home Care Pump AC Version	Ila	36777	all production
014.0012	Clario Home Care Pump AC Version	Ila	36777	all production
014.0013	Clario Home Care Pump AC Version	Ila	36777	all production
014.0014	Clario Home Care Pump AC Version	Ila	36777	all production
014.0015	Clario Home Care Pump AC Version	Ila	36777	all production
014.0020	Clario Home Care Pump AC Version	Ila	36777	all production
014.0040	Clario Home Care Pump AC Version	Ila	36777	all production
014.0050	Clario Home Care Pump AC Version	Ila	36777	all production
014.0110	Clario Home Care Pump AC/DC Version	Ila	36777	all production
014.0111	Clario Home Care Pump AC/DC Version	Ila	36777	all production
014.0112	Clario Home Care Pump AC/DC Version	Ila	36777	all production
014.0113	Clario Home Care Pump AC/DC Version	Ila	36777	all production
014.0114	Clario Home Care Pump AC/DC Version	Ila	36777	all production
014.0115	Clario Home Care Pump AC/DC Version	Ila	36777	all production
014.0120	Clario Home Care Pump AC/DC Version	Ila	36777	all production
014.0140	Clario Home Care Pump AC/DC Version	Ila	36777	all production
014.0150	Clario Home Care Pump AC/DC Version	Ila	36777	all production
014.0210	Clario Home Care Pump Deluxe Version	Ila	36777	all production
014.0211	Clario Home Care Pump Deluxe Version	Ila	36777	all production
014.0212	Clario Home Care Pump Deluxe Version	Ila	36777	all production
014.0213	Clario Home Care Pump Deluxe Version	Ila	36777	all production
014.0214	Clario Home Care Pump Deluxe Version	Ila	36777	all production
014.0215	Clario Home Care Pump Deluxe Version	Ila	36777	all production
014.0220	Clario Home Care Pump Deluxe Version	Ila	36777	all production
014.0230	Clario Home Care Pump Deluxe Version	Ila	36777	all production
014.0240	Clario Home Care Pump Deluxe Version	Ila	36777	all production
014.0250	Clario Home Care Pump Deluxe Version	Ila	36777	all production
020.0501	Surgical Suction Pump Powered from a Pressure Source	Ila	36778	all production
026.2110	Vario Secretion Aspirator	Ila	36777	all production
026.2112	Vario Secretion Aspirator	Ila	36777	all production
026.2113	Vario Secretion Aspirator	Ila	36777	all production
026.2120	Vario Secretion Aspirator	Ila	36777	all production
026.2140	Vario Secretion Aspirator	Ila	36777	all production
026.2150	Vario Secretion Aspirator	Ila	36777	all production
026.2160	Vario Secretion Aspirator	Ila	36777	all production
026.9000	Vario Secretion Aspirator	Ila	36777	all production
026.9001	Vario Secretion Aspirator	Ila	36777	all production
026.9002	IKRK Vario Secretion Aspirator	Ila	36777	all production
026.0006	Vario 18 Given AC Medium Vacuum Aspirator	Ila	36777	all production
026.0008	Vario 18 Given AC Medium Vacuum Aspirator	Ila	36777	all production
026.0007	Vario 18 Given AC Medium Vacuum Aspirator	Ila	36777	all production
026.5110	Vario Secretion Aspirator AC/DC	Ila	36777	all production
026.5112	Vario Secretion Aspirator AC/DC	Ila	36777	all production
026.5140	Vario Secretion Aspirator AC/DC	Ila	36777	all production
026.5150	Vario Secretion Aspirator AC/DC	Ila	36777	all production
026.5160	Vario Secretion Aspirator AC/DC	Ila	36777	all production
026.7110	Vario Low Vacuum Aspirator	Ila	36777	all production
026.7110	Vario Low Vacuum Aspirator	Ila	36787	all production
026.7112	Vario Low Vacuum Aspirator	Ila	36777	all production
026.7112	Vario Low Vacuum Aspirator	Ila	36787	all production
026.7140	Vario Low Vacuum Aspirator	Ila	36777	all production
026.7140	Vario Low Vacuum Aspirator	Ila	36787	all production
026.7150	Vario Low Vacuum Aspirator	Ila	36777	all production
026.7150	Vario Low Vacuum Aspirator	Ila	36787	all production
026.7160	Vario Low Vacuum Aspirator	Ila	36777	all production
026.7160	Vario Low Vacuum Aspirator	Ila	36787	all production
026.7170	Vario Low Vacuum Aspirator	Ila	36777	all production
026.7170	Vario Low Vacuum Aspirator	Ila	36787	all production
026.8113	Vario 18 c/i Medium Vacuum Aspirator AC/DC	Ila	36777	all production
026.8113	Vario 18 c/i Medium Vacuum Aspirator AC/DC	Ila	20395	all production
026.8121	Vario 18 c/i Medium Vacuum Aspirator AC/DC	Ila	36777	all production
026.8122	Vario 18 c/i Medium Vacuum Aspirator AC/DC	Ila	36777	all production
026.8122	Vario 18 c/i Medium Vacuum Aspirator AC/DC	Ila	20395	all production
026.8142	Vario 18 c/i Medium Vacuum Aspirator AC/DC	Ila	36777	all production
026.8142	Vario 18 c/i Medium Vacuum Aspirator AC/DC	Ila	20395	all production
026.8152	Vario 18 c/i Medium Vacuum Aspirator AC/DC	Ila	36777	all production

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026.8152	Vario 18 c/i Medium Vacuum Aspirator AC/DC	Ila	20395	all production
026.8111	Vario 8 c/i Low Vacuum Aspirator AC/DC	Ila	36777	all production
026.8111	Vario 8 c/i Low Vacuum Aspirator AC/DC	Ila	36787	all production
026.8120	Vario 8 c/i Low Vacuum Aspirator AC/DC	Ila	36777	all production
026.8123	Vario 8 c/i Low Vacuum Aspirator AC/DC	Ila	36777	all production
026.8123	Vario 8 c/i Low Vacuum Aspirator AC/DC	Ila	36787	all production
026.8141	Vario 8 c/i Low Vacuum Aspirator AC/DC	Ila	36777	all production
026.8141	Vario 8 c/i Low Vacuum Aspirator AC/DC	Ila	36787	all production
026.8151	Vario 8 c/i Low Vacuum Aspirator AC/DC	Ila	36777	all production
026.8151	Vario 8 c/i Low Vacuum Aspirator AC/DC	Ila	36787	all production
026.8110	Vario 8 Low Vacuum Aspirator AC/DC	Ila	36777	all production
026.8110	Vario 8 Low Vacuum Aspirator AC/DC	Ila	36787	all production
026.8112	Vario 8 Low Vacuum Aspirator AC/DC	Ila	36777	all production
026.8112	Vario 8 Low Vacuum Aspirator AC/DC	Ila	36787	all production
026.8140	Vario 8 Low Vacuum Aspirator AC/DC	Ila	36777	all production
026.8140	Vario 8 Low Vacuum Aspirator AC/DC	Ila	36787	all production
026.8150	Vario 8 Low Vacuum Aspirator AC/DC	Ila	36777	all production
026.8150	Vario 8 Low Vacuum Aspirator AC/DC	Ila	36787	all production
037.0111	Medela Basic 30 mobile	Ila	36777	all production
037.0112	Medela Basic 30 mobile	Ila	36777	all production
037.0113	Medela Basic 30 mobile	Ila	36777	all production
037.0114	Medela Basic 30 mobile	Ila	36777	all production
037.0115	Medela Basic 30 mobile	Ila	36777	all production
037.0122	Medela Basic 30 mobile	Ila	36777	all production
037.0124	Medela Basic 30 mobile	Ila	36777	all production
037.0214	Medela Basic 30 mobile	Ila	36777	all production
037.0224	Medela Basic 30 mobile	Ila	36777	all production
037.1111	Medela Basic 30 portable	Ila	36777	all production
037.1112	Medela Basic 30 portable	Ila	36777	all production
037.1113	Medela Basic 30 portable	Ila	36777	all production
037.1115	Medela Basic 30 portable	Ila	36777	all production
037.1124	Medela Basic 30 portable	Ila	36777	all production
037.1214	Medela Basic 30 portable	Ila	36777	all production
037.1224	Medela Basic 30 portable	Ila	36777	all production
037.2111	Medela Basic 30 Rack	Ila	36777	all production
037.2112	Medela Basic 30 Rack	Ila	36777	all production
037.2113	Medela Basic 30 Rack	Ila	36777	all production
037.2115	Medela Basic 30 Rack	Ila	36777	all production
037.2124	Medela Basic 30 Rack	Ila	36777	all production
037.2214	Medela Basic 30 Rack	Ila	36777	all production
037.2224	Medela Basic 30 Rack	Ila	36777	all production
037.9000	Medela Basic 30 IRCC	Ila	36777	all production
057.4111	Medela Dominant 35 c/i	Ila	20395	all production
057.4111	Medela Dominant 35 c/i	Ila	36787	all production
057.4111	Medela Dominant 35 c/i	Ila	36777	all production
057.4112	Medela Dominant 35 c/i	Ila	20395	all production
057.4112	Medela Dominant 35 c/i	Ila	36787	all production
057.4112	Medela Dominant 35 c/i	Ila	36777	all production
057.4113	Medela Dominant 35 c/i	Ila	20395	all production
057.4113	Medela Dominant 35 c/i	Ila	36787	all production
057.4113	Medela Dominant 35 c/i	Ila	36777	all production
057.4114	Medela Dominant 35 c/i	Ila	20395	all production
057.4114	Medela Dominant 35 c/i	Ila	36787	all production
057.4114	Medela Dominant 35 c/i	Ila	36777	all production
057.4115	Medela Dominant 35 c/i	Ila	20395	all production
057.4115	Medela Dominant 35 c/i	Ila	36787	all production
057.4115	Medela Dominant 35 c/i	Ila	36777	all production
057.4116	Medela Dominant 35 c/i	Ila	20395	all production
057.4116	Medela Dominant 35 c/i	Ila	36787	all production
057.4116	Medela Dominant 35 c/i	Ila	36777	all production
057.4117	Medela Dominant 35 c/i	Ila	20395	all production
057.4117	Medela Dominant 35 c/i	Ila	36787	all production
057.4117	Medela Dominant 35 c/i	Ila	36777	all production
057.4118	Medela Dominant 35 c/i	Ila	20395	all production
057.4118	Medela Dominant 35 c/i	Ila	36787	all production
057.4118	Medela Dominant 35 c/i	Ila	36777	all production
057.4121	Medela Dominant 35 c/i	Ila	20395	all production
057.4121	Medela Dominant 35 c/i	Ila	36787	all production
057.4121	Medela Dominant 35 c/i	Ila	36777	all production

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057.4214	Medela Dominant 35 c/i	Ila 20395	all production
057.4214	Medela Dominant 35 c/i	Ila 36787	all production
057.4214	Medela Dominant 35 c/i	Ila 36777	all production
057.4224	Medela Dominant 35 c/i	Ila 20395	all production
057.4224	Medela Dominant 35 c/i	Ila 36787	all production
057.4224	Medela Dominant 35 c/i	Ila 36777	all production
057.4225	Medela Dominant 35 c/i	Ila 20395	all production
057.4225	Medela Dominant 35 c/i	Ila 36787	all production
057.4225	Medela Dominant 35 c/i	Ila 36777	all production
057.5111	Medela Dominant 35 c/i	Ila 20395	all production
057.5111	Medela Dominant 35 c/i	Ila 36787	all production
057.5111	Medela Dominant 35 c/i	Ila 36777	all production
057.0111	Medela Dominant 50 mobile	Ila 36787	all production
057.0111	Medela Dominant 50 mobile	Ila 36777	all production
057.0111	Medela Dominant 50 mobile	Ila 36894	all production
057.0112	Medela Dominant 50 mobile	Ila 36787	all production
057.0112	Medela Dominant 50 mobile	Ila 36777	all production
057.0112	Medela Dominant 50 mobile	Ila 36894	all production
057.0113	Medela Dominant 50 mobile	Ila 36787	all production
057.0113	Medela Dominant 50 mobile	Ila 36777	all production
057.0113	Medela Dominant 50 mobile	Ila 36894	all production
057.0114	Medela Dominant 50 mobile	Ila 36787	all production
057.0114	Medela Dominant 50 mobile	Ila 36777	all production
057.0114	Medela Dominant 50 mobile	Ila 36894	all production
057.0115	Medela Dominant 50 mobile	Ila 36787	all production
057.0115	Medela Dominant 50 mobile	Ila 36777	all production
057.0115	Medela Dominant 50 mobile	Ila 36894	all production
057.0124	Medela Dominant 50 mobile	Ila 36787	all production
057.0124	Medela Dominant 50 mobile	Ila 36777	all production
057.0124	Medela Dominant 50 mobile	Ila 36894	all production
057.0214	Medela Dominant 50 mobile	Ila 36787	all production
057.0214	Medela Dominant 50 mobile	Ila 36777	all production
057.0214	Medela Dominant 50 mobile	Ila 36894	all production
057.0224	Medela Dominant 50 mobile	Ila 36787	all production
057.0224	Medela Dominant 50 mobile	Ila 36777	all production
057.0224	Medela Dominant 50 mobile	Ila 36894	all production
057.2111	Medela Dominant 50 Rack	Ila 36787	all production
057.2111	Medela Dominant 50 Rack	Ila 36777	all production
057.2111	Medela Dominant 50 Rack	Ila 36894	all production
057.2112	Medela Dominant 50 Rack	Ila 36787	all production
057.2112	Medela Dominant 50 Rack	Ila 36777	all production
057.2112	Medela Dominant 50 Rack	Ila 36894	all production
057.2113	Medela Dominant 50 Rack	Ila 36787	all production
057.2113	Medela Dominant 50 Rack	Ila 36777	all production
057.2113	Medela Dominant 50 Rack	Ila 36894	all production
057.2115	Medela Dominant 50 Rack	Ila 36787	all production
057.2115	Medela Dominant 50 Rack	Ila 36777	all production
057.2115	Medela Dominant 50 Rack	Ila 36894	all production
057.2124	Medela Dominant 50 Rack	Ila 36787	all production
057.2124	Medela Dominant 50 Rack	Ila 36777	all production
057.2124	Medela Dominant 50 Rack	Ila 36894	all production
057.2214	Medela Dominant 50 Rack	Ila 36787	all production
057.2214	Medela Dominant 50 Rack	Ila 36777	all production
057.2214	Medela Dominant 50 Rack	Ila 36894	all production
057.2224	Medela Dominant 50 Rack	Ila 36787	all production
057.2224	Medela Dominant 50 Rack	Ila 36777	all production
057.2224	Medela Dominant 50 Rack	Ila 36894	all production
079.0000	Medela THOPAZ	Ila 36787	all production
079.0002	Medela THOPAZ	Ila 36787	all production
079.0003	Medela THOPAZ	Ila 36787	all production