

DECLARATION OF CONFORMITY FOR THE MEDICAL DEVICE FAMILY "VACUUM ADJUSTMENT SYSTEMS"

whose codes are specified in the attachment, to the essential requirements described in Annex I of Directive 93/42/EEC, as amended by Directive 2007/47/EC and as prescribed by Annex II of Directive 93/42/EEC and following amendments.

FLOW METER S.p.A., with registered office address Largo Porta Nuova, 14 Bergamo - I, headquarters and production site address Via del Lino, 6, Levate (BG) - I, manufacturer of the medical devices named "VACUUM ADJUSTMENT SYSTEMS", whose codes are reported in the attachment,

declares under its own responsibility that the devices in question satisfy all the essential requirements of Annex I of Directive on Medical Devices 93/42/EEC, amended by Directive 2007/47/EC.


For this purpose it hereby guarantees and declares under its own responsibility that:

1. The devices in question satisfy the dispositions applicable under Directive 93/42/EEC, amended by Directive 2007/47/EC.
2. The devices in question should be considered as belonging to Class II A, following rule 11 of Annex IX of the above mentioned Directives.
3. The devices in question are sold in NON STERILE packaging.
4. The devices in question are manufactured in different versions as stated in the list of product codes in the attachment.
5. The design and manufacturing procedures comply with the requirements of the Company Quality System, as prescribed in the Annex II of the a.m. Directive.
6. The Product Technical File will be filed and available to the Notified Body, as specified by Annex II of Directive 93/42/EEC of reference, amended by Directive 2007/47/EC, for a period of at least ten years from the last placing on the market of the product with the last product batch.
7. The a.m. medical devices comply with all the requirements of the following standards:
 - EN ISO 10079-3 "Medical suction equipment - Part 3: Suction equipment powered from a vacuum or pressure source".
8. The devices in question have been designed, manufactured and placed on the market as indicated in the Product Technical File and according to the company Quality System declared to be compliant by CERTIQUALITY, Notified Body number 0546 according to Directive 93/42/EEC, as prescribed in annex II of the aforementioned Directive amended by Directive 2007/47/EC (certificate no. 16655/1, first issue of 08/02/2011, current issue of 24/06/2014 and valid up to 06/06/2017). This system, adopted for the design and manufacturing of all devices, is declared as conforming to standards ISO 9001:2008 (ref. Certificate no. 421, current issue of 07/06/2012) and EN ISO 13485:2012 (ref. Certificate no. 10627, current issue of 28/12/2012).
9. The placing on the market of the above mentioned devices has already been notified to the Italian Competent Authority by FLOW METER S.p.A.. A suitable procedure has been established and is maintained in order to guarantee the post-marketing surveillance required by Directive 93/42/EEC, amended by Directive 2007/47/EC.

This declaration of conformity content is confirmed at every placing on the market of a new device batch, manufactured since 24/06/2014. This declaration of conformity is valid until the expiry date of the certificate.

Attachments: List of models with codes to which this declaration refers;
Copy of EC marking certificate.

Witnessed
Flow Meter S.p.A.
The legal representative
Roberto Paratico



Date of issue of the declaration: 24/06/2014 - Ed. / Is.: 03/1

Attachment 01 – List of models – Updated 24/06/2014

Code	Model
000010001	Vacuum regulator type Easyvac 600 mbar inlet= 1/4" gas M. - outlet= 1/2" gas M.
000010003	Vacuum regulator type Easyvac 1000 mbar inlet=1/4" gas M. - outlet=1/2" gas M.
000010004	Vacuum regulator type Easyvac 250 mbar inlet=1/4" gas M. - outlet=1/2" gas M.
000010005	Vacuum regulator type Easyvac 1000 mbar 1180-000869
000010006	Vacuum regulator type Easyvac 1000 mbar inlet=1/4" gas m. - outlet=3/8" gas M.
000010007	Vacuum regulator 1180-311290
000010008	Vacuum regulator type Easyvac 250 mbar inlet=1/4" gas M. - outlet=3/8" gas M.
000010009	Vacuum regulator type Easyvac 1000 mbar inlet=1/4" gas F. - outlet=1/2" gas M.
000010010	Vacuum regulator type Easyvac 600 mbar inlet=1/4" gas M. – outlet=hose connector
000010011	Vacuum regulator type Easyvac 250 mbar inlet=1/4" gas M. - outlet=hose connector
000010013	Vacuum regulator type Easyvac 1000 mbar inlet=M16x1,25 M. - outlet=hose connector
000010014	Vacuum regulator type Easyvac 600 mbar inlet=M16x1,25 M. - outlet=hose connector
000010016	Vacuum regulator type Easyvac 1000 mbar inlet=1/4" gas M. - outlet=hose connector
000010017	Vacuum regulator type Easyvac 250 mbar inlet=M12x1 F. - outlet=1/2" gas M.
000010018	Vacuum regulator type Easyvac 600 mbar inlet=M12x1 F. - outlet=1/2" gas M.
000010019	Vacuum regulator type Easyvac 1000 mbar inlet=M12x1 M. - outlet=1/2" gas M.
000010022	Vacuum regulator type Easyvac 250 mbar inlet=probe for wall outlet AFNOR - outlet=1/2" gas M.
000010023	Vacuum regulator type Easyvac 600 mbar inlet=probe for wall outlet AFNOR - outlet=1/2" gas M.
000010024	Vacuum regulator type Easyvac 1000 mbar inlet=probe for wall outlet AFNOR - outlet=1/2" gas M.
000010025	Vacuum regulator type Easyvac 250 mbar inlet=bracket for rail 30x10 - outlet=1/2" gas M.
000010026	Vacuum regulator type Easyvac 600 mbar inlet=bracket for rail 30x10 - outlet=1/2" gas M.
000010027	Vacuum regulator type Easyvac 1000 mbar inlet=bracket for rail 30x10 - outlet=1/2" gas M.
000010028	Vacuum regulator type Easyvac 1000 mbar inlet= M16x1,25 M. - outlet=1/2" gas M.

Code	Model
000010030	Vacuum regulator type Easyvac 600 mbar inlet=M16x1,25 M. - outlet=1/2" gas M.
000010031	Vacuum regulator type Easyvac 250 mbar inlet=probe for wall outlet AFNOR - outlet=1/2" gas M.
000010032	Vacuum regulator type Easyvac 600 mbar inlet=probe for wall outlet AFNOR - outlet=1/2" gas M.
000010033	Vacuum regulator type Easyvac 1000 mbar inlet=probe for wall outlet AFNOR - outlet=1/2" gas M.
000010034	Vacuum regulator type Easyvac 250 mbar inlet=probe for wall outlet UNI - outlet=1/2" gas M.
000010035	Vacuum regulator type Easyvac 600 mbar inlet=probe for wall outlet UNI - outlet=1/2" gas M.
000010036	Vacuum regulator type Easyvac 1000 mbar inlet=probe for wall outlet UNI - outlet=1/2" gas M.
000010040	Vacuum regulator type Easyvac 250 mbar inlet=DIN 13260 probe - outlet=1/2" gas M.
000010041	Vacuum regulator type Easyvac 600 mbar inlet=DIN 13260 probe - outlet=1/2" gas M.
000010042	Vacuum regulator type Easyvac 1000 mbar inlet=DIN 13260 probe - outlet=1/2" gas M.
000010043	Vacuum regulator type Easyvac 250 mbar inlet=plastic bracket for rail 30x10-1.5 M. Hose-DIN 13260 probe - outlet=1/2" gas M.
000010044	Vacuum regulator type Easyvac 600 mbar inlet=plastic bracket for rail 30x10-1.5 M. Hose-DIN 13260 probe - outlet=1/2" gas M.
000010045	Vacuum regulator type Easyvac 1000 mbar inlet=plastic bracket for rail 30x10-1.5 M. Hose-DIN 13260 probe - outlet=1/2" gas M.
000010130	Vacuum regulator Easyval/250 complete with Antibacteria safety jar Mak/300 134°C, hydrophobic filter, plastic bracket for rail 30x10 M., 0.8 M. Hose EN 739 and probe Easyfix for AFNOR NF-S 90-116 outlet
000010131	Vacuum regulator Easyval/600 complete with Antibacteria safety jar Mak/300 134°C, hydrophobic filter, plastic bracket for rail 30x10 M., 0.8 M. Hose EN 739 and probe Easyfix for AFNOR NF-S 90-116 outlet
000010132	Vacuum regulator Easyval/1000 complete with Antibacteria safety jar Mak/300 134°C, hydrophobic filter, plastic bracket for rail 30x10 M., 0.8 M. Hose EN 739 and probe Easyfix for AFNOR NF-S 90-116 outlet
000010133	Vacuum regulator type Easyval/250 mbar with ABS bracket for rail 30 x 10, 1,5 m hose, probe AFNOR NF-S 90-116 Easyfix, Easysafe safety jar with hydrophobic filter

Code	Model
000010134	Vacuum regulator type Easyval/600 mbar with ABS bracket for rail 30 x 10, 1,5 m hose, probe AFNOR NF-S 90-116 Easyfix, Easysafe safety jar with hydrophobic filter
000010135	Vacuum regulator type Easyval/1000 mbar with ABS bracket for rail 30 x 10, 1,5 m hose, probe AFNOR NF-S 90-116 Easyfix, Easysafe safety jar with hydrophobic filter
000010136	Vacuum regulator Easyval/250 with BS inlet with Easysafe and filter
000010137	Vacuum regulator Easyval/600 with BS inlet with Easysafe and filter
000010138	Vacuum regulator Easyval/1000 with BS inlet with Easysafe and filter
000010140	Vacuum regulator Easyval/250 complete with self-locking probe for AFNOR NF-S 90-116 outlet, Antibacteria safety jar Mak/300 134°C, hydrophobic filter
000010141	Vacuum regulator Easyval/600 complete with self-locking probe for AFNOR NF-S 90-116 outlet, Antibacteria safety jar Mak/300 134°C, hydrophobic filter
000010142	Vacuum regulator Easyval/1000 complete with self-locking probe for AFNOR NF-S 90-116 outlet, Antibacteria safety jar Mak/300 134°C, hydrophobic filter
000010143	Vacuum regulator type Easyval 600 mbar inlet=cm probe - with safety jar Easysafe and filter
000010144	Vacuum regulator type Easyval 250 mbar inlet=cm probe - with safety jar Easysafe and filter
000010145	Double vacuum regulator type Easyval 600 mbar inlet=DIN 12260 probe - with safety jar Easysafe and filter
000010146	Vacuum regulator type Easyval 1000 mbar inlet=DIN 12260 probe - with safety jar Easysafe and filter
000010147	Double vacuum regulator type Easyval 1000 mbar inlet=DIN 12260 probe - with safety jar Easysafe and filter
000010148	Vacuum regulator type Easyval 600 mbar inlet=1/4" M. - with safety jar Easysafe and filter
000010149	Vacuum regulator Easyval/1000 with 30x10 plastic bracket, for rail 1.5 m.
000010150	Vacuum regulator Easyval/250 complete with probe Easyfix for AFNOR NF-S 90-116 outlet, Antibacteria safety jar Mak/300 134°C, hydrophobic filter
000010151	Vacuum regulator Easyval/600 complete with probe Easyfix for AFNOR NF-S 90-116 outlet, Antibacteria safety jar Mak/300 134°C, hydrophobic filter
000010152	Vacuum regulator Easyval/1000 complete with probe Easyfix for AFNOR NF-S 90-116 outlet, Antibacteria safety jar Mak/300 134°C, hydrophobic filter
000010153	Vacuum regulator Easyval 600 with 30x10 plastic bracket, for rail 1.5 m.

Code	Model
000010154	Vacuum regulator Easyval 250 with 30x10 plastic bracket, for rail 1.5 m.
000010155	Vacuum regulator Easyval 1000 with inlet cm - outlet=hose holder
000010156	Vacuum regulator Easyval 250 with inlet cm - outlet=hose holder
000010157	Vacuum regulator Easyval 1000 with 30x10 plastic bracket, for rail 1.5 m.
000010158	Vacuum regulator Easyval 600 with 30x10 plastic bracket, for rail 1.5 m.
000010159	Vacuum regulator Easyval 250 with 30x10 plastic bracket, for rail 1.5 m.
000010160	Vacuum regulator Easyval/250 complete with self-locking probe for AFNOR NF-S 90-116 outlet with tubing connector
000010161	Vacuum regulator Easyval/600 complete with self-locking probe for AFNOR NF-S 90-116 outlet with tubing connector
000010162	Vacuum regulator Easyval/1000 complete with self-locking probe for AFNOR NF-S 90-116 outlet with tubing connector
000010163	Vacuum regulator type Easyval 600 mbar inlet=cm probe - outlet=hose connector
000010164	Vacuum regulator Easyval 1000 with inlet DIN- outlet=hose holder
000010165	Vacuum regulator Easyval 600 with inlet DIN- outlet=hose holder
000010166	Vacuum regulator Easyval 250 with inlet DIN- outlet=hose holder
000010167	Vacuum regulator Easyval 1000 with 30x10 plastic bracket, for rail 1.5 m.
000010168	Vacuum regulator Easyval 600 with 30x10 plastic bracket, for rail 1.5 m.
000010169	Vacuum regulator Easyval 250 with 30x10 plastic bracket, for rail 1.5 m.
000010170	Vacuum regulator Easyval/250 complete with probe Easyfix for AFNOR NF-S 90-116 outlet, Antibacteria safety jar Mak/300 134°C, hydrophobic filter
000010171	Vacuum regulator Easyval/600 complete with probe Easyfix for AFNOR NF-S 90-116 outlet, Antibacteria safety jar Mak/300 134°C, hydrophobic filter
000010172	Vacuum regulator Easyval/1000 complete with probe Easyfix for AFNOR NF-S 90-116 outlet, Antibacteria safety jar Mak/300 134°C, hydrophobic filter
000010173	Vacuum regulator Easyval/1000 inlet cm and Easysafe safety jar+filter
000010174	Vacuum regulator Easyval 1000 with 30x10 plastic bracket, for rail 1.5 m.
000010175	Vacuum regulator Easyval 600 with 30x10 plastic bracket, for rail 1.5 m.

Code	Model
000010176	Vacuum regulator Easyval 250 with 30x10 plastic bracket, for rail 1.5 m.
000010177	Vacuum regulator Easyval 600 inlet BS outlet=1/2" m.
000010178	Vacuum regulator Easyval 600 inlet DIN and Easysafe safety jar+filter
000010179	Vacuum regulator Easyval 250 inlet DIN and Easysafe safety jar+filter
000010180	Vacuum regulator Easyval 600 with 30x10 plastic bracket, for rail 1.5 m.
000010181	Vacuum regulator Easyval 250 with 30x10 plastic bracket, for rail 1.5 m.
000010182	Vacuum regulator Easyval1000 double inlet AFNOR – Easysafe safety jar
000010183	Vacuum regulator Easyval 600 double inlet AFNOR - Easysafe safety jar
000010184	Vacuum regulator Easyval 250 double inlet AFNOR - Easysafe safety jar
000010185	Vacuum regulator Easyval 1000 double inlet cm – Easysafe safety jar+filter
000010186	Vacuum regulator Easyval 600 double inlet cm - Easysafe safety jar+filter
000010187	Vacuum regulator Easyval 250 double inlet cm - Easysafe safety jar+filter
000010188	Vacuum regulator Easyval 250 double inlet DIN - Easysafe safety jar+filter
000551000	Vacuum regulator Easyvac Plus 250 mbar inlet 1/4"gas M.-outlet.1/2"gas M.
000551001	Vacuum regulator Easyvac Plus 600 mbar inlet 1/4"gas M.-outlet 1/2"gas M.
000551002	Vacuum regulator Easyvac Plus 1000 mbar inlet 1/4"gas M.-outlet 1/2"gas M.



ISTITUTO DI CERTIFICAZIONE DELLA QUALITÀ
ORGANISMO NOTIFICATO N° 0546
NOTIFIED BODY N° 0546

APPROVAZIONE DEL SISTEMA DI QUALITÀ ATTUATO DA
APPROVAL OF THE QUALITY SYSTEM OPERATED BY

FLOW METER S.p.A.
IT - 24100 BERGAMO (BG) - LARGO PORTA NUOVA 14

UNITÀ OPERATIVE
OPERATING SITES
IT - 24040 LEVATE (BG) - VIA DEL LINO 6

PER I SEGUENTI TIPI/FAMIGLIE DI PRODOTTI
FOR THE FOLLOWING TYPES/CLASSES OF PRODUCTS

Dispositivi per applicazioni con gas medicinali
Devices for uses with medical gas

Certiquality S.r.l., Organismo Notificato n° 0546, certifica che il sistema garanzia qualità
Certiquality S.r.l., Notified Body n°0546, certifies that the quality assurance system

è conforme ai requisiti della Direttiva 93/42 CEE, Allegato
is in compliance with the requirements of Council Directive 93/42/EEC, Annex



ad esclusione del punto 4
excluding section 4

CERTIFICATO N.
CERTIFICATE N.

16655/1

IL PRESENTE CERTIFICATO NON È DA RITENERSI VALIDO SE NON ACCOMPAGNATO DAL RELATIVO ALLEGATO
THIS CERTIFICATE IS NOT VALID WITHOUT THE RELEVANT ANNEX

PRIMA EMISSIONE
FIRST ISSUE 08/02/2011

EMISSIONE CORRENTE
CURRENT ISSUE 24/06/2014

DATA DI SCADENZA
EXPIRY DATE 06/06/2017

Il Direttore Generale

CERTIQUALITY S.r.l.

CERTIQUALITY S.r.l. ISTITUTO DI CERTIFICAZIONE DELLA QUALITÀ
Via Gaetano Giardino 4 - 20123 Milano - tel. 02 8069171 - fax 02 86465295 - certiquality@certiquality.it - www.certiquality.it



ISTITUTO DI CERTIFICAZIONE DELLA QUALITÀ

ORGANISMO NOTIFICATO N° 0546

NOTIFIED BODY N° 0546

ALLEGATO AL CERTIFICATO N. 16655/1
ANNEX TO CERTIFICATE N.

FLOW METER S.p.A.

ELENCO PRODOTTI / LIST OF PRODUCTS

Aspiratori Venturi
Venturi Suction Units

Unità flussometriche per anestesia
Flowmeters for anaesthesia

Sistemi di regolazione del vuoto
Vacuum adjustment systems.

Flussimetri per gas medicinali
Flowmeters devices for medical gases

Riduttori di pressione e riduttori di pressione con flussimetri
(serie FM, versione per installazioni standard e per installazioni in ambulanze - serie MU - serie EASYCARE)
Pressure regulators and pressure regulators with flowmeters devices
(type FM, standard or for ambulance applications - type MU - type EASYCARE)

Umidificatori per uso medicale
Humidifiers for medical use

Unità terminali per gas medicinali compressi e vuoto e per sistemi di evacuazione gas anestetici
Terminal units for compressed medical gases and vacuum and for anaesthetic gas scavenging systems

Valvola riduttrice MERCURY
Pressure regulator with cylinder valve type MERCURY

Tubi flessibili per bassa pressione per l'impiego con gas medicinali
Low-pressure hose assemblies for use with medical gases

Impianti per la distribuzione dei gas medicinali in ambulanze
Pipeline systems for medical gases on road ambulances

IL PRESENTE ALLEGATO NON E' DA RITENERSI VALIDO SE NON ACCOMPAGNATO DAL RELATIVO CERTIFICATO
THIS ANNEX IS NOT VALID WITHOUT THE RELEVANT CERTIFICATE

PRIMA EMISSIONE
FIRST ISSUE 08/02/2011

EMISSIONE CORRENTE
CURRENT ISSUE 24/06/2014

DATA DI SCADENZA
EXPIRY DATE 06/06/2017

Il Direttore Generale

CERTIQUALITY S.r.l.

CERTIQUALITY S.r.l. ISTITUTO DI CERTIFICAZIONE DELLA QUALITÀ

Via Gaetano Giardino 4 - 20123 Milano - tel. 02 8069171 - fax 02 86465295 - certiquality@certiquality.it - www.certiquality.it