

DECLARATION OF CONFORMITY FOR THE MEDICAL DEVICE FAMILY "PRESSURE REGULATORS AND PRESSURE REGULATORS WITH FLOW-METERING DEVICES"

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 and operation site in Via del Lino, 6, zip code 24040 - Levate (BG) - I, manufacturer of the medical devices named "**PRESSURE REGULATORS AND PRESSURE REGULATORS WITH FLOW-METERING DEVICES**", 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 B, 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 10524-1 "Pressure regulators for use with medical gases - Part 1: Pressure regulators and pressure regulators with flow-metering devices".
8. The devices in question have been 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 26/01/2015 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) and EN ISO 13485:2012 (ref. certificate no. 10627).
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 18/01/2017. 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: 18/01/2017 - Ed. / Is.: 03/9

Attachment 01 – List of models – Updated 18/01/2017

FM model list	
Code	Description
S00000010	Pressure regulator FM for O2 – Inlet : UNI 4406 with flowmeter Rs 15 LPM (ABS knob) and humidifier TR/200
000090000	Pressure regulator FM for O2 – Inlet : UNI 4406 – Outlet : hose connector
000090001	Pressure regulator FM for O2 – Inlet : UNI 4406 long type – Outlet : hose connector
000090003	Pressure regulator FM for O2 – Inlet : UNI 4406 – Outlet : G ¼" F.
000090004	Pressure regulator FM for nitrogen – Inlet : UNI 4409 – Outlet : hose connector
000090005	Pressure regulator FM for O2 – Inlet : BS 341 – Outlet : hose connector
000090006	Pressure regulator FM for O2 – Inlet : UNI 4406 – Outlet: angle connection for PE hose Ø6x4 with spring
000090007	Pressure regulator FM for nitrogen - Inlet : UNI 4409 - U=G. 1/4" F.
000090008	Pressure regulator FM for N2O – Inlet : UNI 9097 – U. G ¼" F.
000090009	Pressure regulator FM for O2 – Inlet : UNI 4406 with flowmeter Rs 10 LPM 9/16" UNF
000090010	Pressure regulator FM for AIR – Inlet : UNI 4410 – Outlet : hose connector
000090011	Pressure regulator FM for AIR – Inlet : UNI 4410 – U. G ¼" F.
000090012	Pressure regulator FM for O2 – Inlet : UNI 4406 long type – U. G ¼" F.
000090018	Pressure regulator FM for O2 – Inlet : DIN 477 – Outlet : hose connector
000090019	Pressure regulator FM for AIR – Inlet : DIN 477 – Outlet : hose connector
000090020	Pressure regulator FM for AIR with double pressure gauge – Inlet : UNI 4410 – Outlet : hose connector - without knob
000090021	Pressure regulator FM for O2 with double pressure gauge – Inlet : UNI 4406 – Outlet : hose connector - without knob
000090023	Pressure regulator FM for He with double pressure gauge – Inlet : UNI 4412 – Outlet : hose connector
000090024	Pressure regulator FM for O2 with double pressure gauge – Inlet : UNI 4406 with flowmeter Rs 15 LPM
000090025	Pressure regulator FM for CO2 – Inlet : UNI – Outlet : hose connector
000090026	Pressure regulator FM for O2 – Inlet : EN 850 – Outlet : hose connector
000090028	Pressure regulator FM for O2 – Inlet : UNI 4406 – U. with terminal unit UNI 9507
000090029	Pressure regulator FM for O2 – Inlet : UNI 10751 – Outlet : hose connector
000090030	Pressure regulator FM for O2 – Inlet : EN 850 with flowmeter Rs 15 LPM
000090031	Pressure regulator FM for O2 – Inlet : UNI 10751 – Outlet : angle hose connector
000090032	Pressure regulator FM for O2 – Inlet : UNI 10751 – U. G ¼" F.
000090033	Pressure regulator FM for O2 – Inlet : DIN 477 – U. G. ¼" F.
000090034	Pressure regulator FM for AIR with double pressure gauge – Inlet : UNI 4410 – Outlet : hose connector - with knob
000090035	Pressure regulator FM for O2 with double pressure gauge – Inlet : UNI 4406 – Outlet : hose connector - with knob
000090036	Pressure regulator FM for O2 – Inlet : UNI 10751 – Outlet : elbow hose connector
000090039	FM pressure regulator for O2 with UNI 10751 inlet and hoseholder outlet with signal 0.5-4.5 V.
000090040	Pressure regulator FM for O2 with double pressure gauge – Inlet : UNI 4406 long type – Outlet : hose connector - without knob
000090041	Pressure regulator FM for O2 with double pressure gauge – Inlet : UNI 4406 long type – Outlet : hose connector - with knob
000090042	Pressure regulator FM for N2O – Inlet : DIN on right side – Outlet : hose connector downwards
000090043	Pressure regulator FM for O2 – Inlet : DIN 477 on right side – Outlet : hose connector downwards
000090044	Pressure regulator FM for N2O Inlet=BS 341 – Outlet: hose connector
000090045	Pressure regulator FM O2 double gauge - Inlet: BS 341 - Outlet: hose connector with adjusting knob
000090046	Pressure regulator FM O2 double gauge connection DIN 477 with adjusting knob
000090047	Pressure regulator FM O2 double gauge - Inlet: BS 341 - Outlet: hose connector with adjusting knob
000090048	Pressure regulator FM for N2O double gauge - Inlet BS 341 with adjusting knob
000090049	Pressure regulator FM for CO2 double gauge - Inlet BS 341 with adjusting knob
000090050	Pressure regulator FM for N2O – Inlet: UNI 9097 – Outlet : hose connector
000090051	Pressure regulator FM O2 – with continuous proportional electric signal – Inlet: DIN 477 – Outlet: hose connector
000090052	Pressure regulator FM O2 – double gauge with adjusting knob – Inlet: pin-index – Outlet: hose connector
000090053	Pressure regulator FM double gauge for helium with knob -Inlet UNI 4412 Outlet hose connection
000090054	Pressure regulator FM double gauge for air - Inlet cylinder connection BS 341 - Outlet hose connection
000090061	Pressure regulator FM for CO2 inlet cylinder connection BS341 outlet hose connector

000090062	Pressure regulator FM O2 Inlet=CGA-540 - Outlet=hose connector
000090063	Pressure regulator FM air Inlet=CGA-346 - Outlet=hose connector
000090064	Pressure regulator FM N2O Inlet=CGA-910 - Outlet=hose connector
000090065	Pressure regulator FM Entonox Inlet=CGA-280 - Outlet=hose connector
000090066	Pressure regulator FM CO2 Inlet=CGA-320 - Outlet=hose connector
000090067	Pressure regulator FM various gases – Inlet: CGA-580 - Outlet: hose connector
000090068	Pressure regulator FM O2 - Cylinder inlet connection pin-index - with Rs flowmeter 15 l/min O2 outlet 3/8" M.
000090090	Pressure regulator FM oxygen Inlet : AFNOR NF-E 29-656 – Outlet : hose connector
000090091	Pressure regulator FM for O2 with double pressure gauge – Inlet : NF E 29-656 – Outlet : hose connector
000090092	Pressure regulator FM for AIR – Inlet : NF E 29-652 – Outlet : hose connector
000090093	Pressure regulator FM for O2 – Inlet : NF E29-656 – Outlet : elbow 1/4" F.
000090094	Pressure regulator FM for Air double gauge – Inlet : NF E29-652 – Outlet : hose connector
000090095	Pressure regulator FM for O2 Inlet=NF E29-656 - Outlet=3/8" ISO 3253 M.
000090096	Pressure regulator FM double gauge for O2 no knob Inlet=NF E29-656 Outlet=hose connection
000090097	Pressure regulator FM double gauge for CO2 with knob cylinder connection UNI - Outlet 1/4"
000090098	Pressure regulator FM for O2 cylinder connect. UNE W22,91x1/14 type F - Outlet hose connection
000090110	Pressure regulator FM for N2O double gauge – Inlet : NF E29-657 – Outlet : hose connector
000090111	Pressure regulator FM for N2O – Inlet: NF E 29-657– Outlet : hose connector
000090118	Pressure regulator FM for O2 – Inlet: UNI 4406 – U. 9/16" UNF M.
000090119	Pressure regulator FM for CO2 with 2 gauges - Inlet: NF E29-657 Outlet: hose connector
000090120	Pressure regulator FM for CO2 with 1 gauge - Inlet: NF E29-657 Outlet: hose connector
000090200	Pressure regulator FM for N2O with double pressure gauge – Inlet : UNI 9097 – Outlet : hose connector - without knob
000090201	Pressure regulator FM for N2O with double pressure gauge – Inlet : UNI 9097 – Outlet : hose connector - with knob
000090251	Pressure regulator FM for CO2 with double pressure gauge – Inlet : UNI – Outlet : hose connector - without knob
000090252	Pressure regulator FM for CO2 with double pressure gauge – Inlet : UNI – Outlet : hose connector - with knob
000090400	Pressure regulator FM for nitrogen with double pressure gauge – Inlet : UNI – Outlet : hose connector - without knob
000090401	Pressure regulator FM for nitrogen with double pressure gauge – Inlet : UNI – Outlet : hose connector - with knob
000091051	Pressure regulator FM for O2 – Inlet : DIN 477 with flowmeter Rs 15 LPM 9/16" UNF
000091052	Pressure regulator FM for AIR – Inlet : DIN 477 with flowmeter Rs 15 LPM 9/16" UNF
000091053	Pressure regulator FM O2 - conn. to the cylinder: BS 341 with flowmeter Rs 10 l/min. - Outlet: 1/4" M.
000091054	Pressure regulator FM O2 with Rs flowmeter 15 l/min Inlet connection: DIN477 Outlet connection: 1/4" M
000091055	Pressure regulator FM O2 BS 341 connection with Rs flowmeter 15 l/m Outlet=1/4"
000091056	Pressure regulator FM for O2 + Rs 15 l/m cylinder conn. DIN 477-1 Outlet 1/4" M.
000091061	Pressure regulator FM for O2 – Inlet : UNI 10751 with flowmeter Rs 15 LPM 9/16" UNF and hose connector
000091064	Pressure regulator FM for nitrogen with flowmeter Rs 4 l/min - Outlet : hose connector
000091066	Pressure regulator FM for O2 – Inlet : UNI 10751 with flowmeter Rs 10 LPM not compensated
000091067	Pressure regulator FM for O2 – Inlet UNI 10751 with flowmeter Rs 4 l/min Outlet=1/4 with hose connector
000091068	Pressure regulator FM for O2 – Inlet UNI 10751 with flowmeter Rs 30 L/MIN. Outlet=1/4 with hose connector
000091089	Pressure regulator FM O2 inlet connection pin-index with flowmeter Rs 15 l/min.O2 outlet 9/16" M.
000091090	Pressure regulator FM for O2 – Inlet : UNI 4406 with flowmeter Rs 15 LPM
000091091	Pressure regulator FM for O2 – Inlet : AFNOR NF-E 29-650 with flowmeter Rs 15 LPM U. 9/16" UNF M. + hose connector
000091092	Pressure regulator FM for O2 – Inlet : UNI 4406 long type - with flowmeter Rs 15 LPM
000091093	Pressure regulator FM for O2 – Inlet : UNI 10751 with flowmeter Rs 15 LP M 1/4"
000091094	Pressure regulator FM for O2 – Inlet: AFNOR NF-E 29-650 with flowmeter Rs 15 L/min. 1/4" M.
000091095	Pressure regulator FM O2 +Rs flowmeter 15 l/m cylinder connection BS 341-3 Outlet=9/16" M
000091096	Pressure regulator FM O2 +Rs flowmeter 50 l/m cylinder connection=BS 341-3 Outlet=9/16" M
000091097	Pressure regulator FM for air + Rs flowmeter 15 l/m cylinder connection BS 341-3 Outlet=9/16" M
000130000	Pressure regulator FM for O2 – Inlet : UNI 4406 with flowmeter Rs 15 LPM and humidifier TR/200
000130001	Pressure regulator FM for O2 – Inlet : UNI 4406 long type - with flowmeter Rs 15 LPM and humidifier TR/200
000130010	Pressure regulator FM for O2 – Inlet : UNI 10751 with flowmeter Rs 15 LPM and humidifier TR/200
000130050	Pressure regulator FM for O2 – Inlet : UNI 4406 with flowmeter Rs 30 LPM and humidifier TR/200
000130060	Pressure regulator FM for O2 – Inlet : NF E 29-656 with flowmeter Rs 15 LPM 1/4" ISO 3253 M. and humidifier TR/200

000130070	Pressure regulator FM for O ₂ – Inlet : NF E 29-656 with flowmeter Rs 15 LPM 9/16" UNF M. and humidifier TR/200
000130080	Pressure regulator FM for O ₂ – Inlet: BS 341 with flowmeter Rs 15 LPM 1/4" M. and humidifier TR/200
000130081	Pressure regulator FM O ₂ connection BS 341 with flowmeter Rs 15 l/min. O ₂ 9/16 and humidifier TR 200
000131000	Pressure regulator FM for O ₂ – Inlet: UNI 4406 with flowmeter Rs 15 LPM 1/4" M. and humidifier MAK/500
000131100	Pressure regulator FM for O ₂ – Inlet : UNI 4406 with flowmeter RsL 15 LPM and humidifier type monobloc MAK/500
000131200	Pressure regulator FM for O ₂ – Inlet : UNI 4406 with flowmeter RsPL 15 LPM and humidifier type monobloc CH/200
000131300	Pressure regulator FM for O ₂ – Inlet : UNI 4406 with flowmeter Rs 15 LPM 9/16" UNF and TR/200 humidifier
000131400	Pressure regulator FM for O ₂ – Inlet : UNI 4406 with flowmeter RsP 15 LPM and humidifier MAK/500
000132000	Pressure regulator FM for O ₂ – Inlet : UNI 4406 with flowmeter Rs 15 LPM and humidifier CH/200
000132010	Pressure regulator FM for O ₂ – Inlet : UNI 4406 with flowmeter Rs 15 LPM and humidifier CH 200 9/16" UNF
000132100	Pressure regulator FM for O ₂ – Inlet : UNI 4406 with flowmeter Rs 5 LPM and humidifier TR/200
000132200	Pressure regulator FM for O ₂ – Inlet : NF E 29-656 with flowmeter Rs 15 LPM 9/16" UNF and humidifier TR/200
000132201	Pressure regulator FM for O ₂ – Inlet : NF E 29-656 with flowmeter Rs 15 LPM M12x1.25 and humidifier TR/200
000132202	Pressure regulator FM for O ₂ – Inlet : AFNOR type F with flowmeter Rs 15 LPM M12x1.25 and humidifier TR/200
000132203	Pressure regulator FM cylinder AFNOR connection + Rs flowmeter 15 L/min + humidifier MAK/300 inlet thread 12x1,25
000132300	Pressure regulator FM for O ₂ – Inlet : DIN 477 with flowmeter Rs 15 LPM G 1/4" and humidifier TR/200
000132301	Pressure regulator FM O ₂ connection DIN 477 with flowmeter Rs 15 l/min.9/16" and humidifier TR
000132302	Pressure regulator FM O ₂ connection pin-index with flowmeter Rs 15 l/min.9/16" and humidifier TR

MU model list

Code	Description
000090112	Pressure regulator MU for O ₂ – Inlet : UNI 10751 – Outlet : hose connector
000090113	Pressure regulator MU for O ₂ – Inlet: EN 850 – Outlet: hose connector
000090114	Pressure regulator MU for AIR – Inlet : UNI 4410 – U. G. 1/8" F.
000090115	Pressure regulator MU for AIR – Inlet : UNI 4410 – Outlet : hose connector
000091031	Pressure regulator MU for O ₂ – Inlet : UNI 10751 – with radial manoflowmeter 9 LPM – Outlet : hose connector
000091033	Pressure regulator MU for O ₂ – Inlet : UNI 10751 – with axial manoflowmeter 9 LPM – Outlet : hose connector
000091034	Pressure regulator MU att. BS 341 - with back connection flowgauge
000091035	Pressure regulator MU for O ₂ – Inlet : EN 850 – with axial manoflowmeter 9 LPM – Outlet : hose connector
000091036	Pressure regulator MU for O ₂ – UNI 4406 with flowmeter RsM 8 L/min. GTF
000091037	Pressure regulator MU for O ₂ – Inlet : DIN 477 – with axial manoflowmeter 9 LPM – Outlet : hose connector
000091038	MU pressure regulator with manoflowmeter, radial AFNOR connector
000091039	Pressure regulator type MU O ₂ with side flow gauge - Connection to the cylinder: DIN 477
000091040	Pressure regulator type MU O ₂ with side flow gauge - Connection: pin-index
000091041	Pressure regulator MU BS 341 connection, with side flow gauge

Easycare model list

Code	Description
000094000	Pressure regulator Easycare for O ₂ 14 L/min. – Inlet : UNI 10751 – Outlet : thread 1/4" ISO 3253 M.
000094001	Pressure regulator Easycare10 O ₂ 14 L/min. Inlet=UNI 10751 Outlet=9/16" UNF M.
000094002	Pressure regulator Easycare10 O ₂ 0.5-14 L/min. Inlet=UNI 10751 Outlet= G. 1/4" M.
000094003	Pressure regulator Easycare10 O ₂ 1-30 L/min. Inlet=UNI 10751 Outlet= G. 1/4" M.
000094004	Pressure regulator Easycare10 O ₂ 6 L/min. Inlet=UNI 10751 Outlet= G. 1/4" M. Vital
000094005	Pressure regulator Easycare O ₂ 5 L/min. – I.= UNI 10751 – O= G1/4"M.
000094006	Pressure regulator Easycare10 O ₂ 1-30 L/m. Inlet=BS 341 Outlet=G. 1/4" M.
000094007	Pressure regulator Easycare10 O ₂ 15 L/m. Inlet=CGA-540 Outlet=9/16" UNF
000094008	Pressure regulator Easycare10 O ₂ 6 L/min. Inlet=UNI 10751 Outlet =G1/4"M.
000094009	Pressure regulator Easycare10 O ₂ 0,5-15 L/min Inlet UNI 10751 Outlet G1/4"M.
000094010	Pressure regulator Easycare for O ₂ 30 L/min. – Inlet : UNI 10751 – Outlet : thread 1/4" ISO 3253 M.

000094011	Pressure regulator Easycare10 O2 1-15 L/m. I=BS 341 O=M 12x1,25 M.
000094015	Pressure regulator Easycare10 O2 14 L/min. Inlet= BS 341 Outlet= M12X1,25 M.
000094016	Pressure regulator Easycare10 O2 15 L/min. Inlet=DIN 477-1 Outlet= 9/16" M. UNF
000094017	Pressure regulator Easycare 10 O2 6 l/min Inlet: DIN 477 - Outlet: 9/16"M. UNF
000094018	Pressure regulator Easycare for O2 15 LPM – Inlet : DIN 477-1 – Outlet : thread 1/4" ISO 3253 M.
000094019	Pressure regulator Easycare for o2 - 14 L/min. - Inlet=din 477-1 - Outlet=9/16"m. UNF
000094020	Pressure regulator Easycare for O2 14 L/min. – Inlet : DIN 477-1 – Outlet : thread 1/4" ISO 3253 M.
000094021	Pressure regulator Easycare for O2 15 LPM – Inlet: BS 341 - Outlet: thread 1/4" ISO 3253 M.
000094022	Pressure regulator Easycare for O2 - 15 L/min. - Inlet=BS341 - Outlet=9/16"M.
000094023	Pressure regulator Easycare for O2 - 14 L/min. - Inlet=NF-E 29-656 - Outlet=G.1/4" M.
000094024	Pressure regulator Easycare for O2 14 LPM – Inlet: AFNOR - Outlet: 9/16" UNF M.
000094025	Pressure regulator Easycare for O2 14 LPM – Inlet: AFNOR - Outlet: M12X1,25 M.
000094026	Pressure regulator Easycare for O2 15 LPM – Inlet: AFNOR - Outlet: M12X1,25 M.
000094027	Pressure regulator Easycare for O2 14 LPM – Inlet: PIN-INDEX - Outlet: M12X1,25 M.
000094028	Pressure regulator Easycare for O2 - 15 L/min. - Inlet=PIN-INDEX - Outlet=9/16"UNF M.
000094029	Pressure regulator Easycare10 AIR 15 L/min. Inlet=AFNOR Outlet=M12x1,25
000094030	Pressure regulator Easycare for O2 15 LPM – Inlet: AFNOR type F - Outlet: M12X1,25 M. with hose connector and outlet type AFNOR
000094031	Pressure regulator Easycare10 for O2 6 LPM – Inlet : AFNOR type F – Outlet : thread M12x1,25 M. VITAL
000094032	Pressure regulator Easycare10 for O2 6 LPM – Inlet : UNE W22,91x1/14 type F – Outlet : thread 9/16" M. VITAL
000094033	Pressure regulator Easycare for O2 15 LPM – Inlet : AFNOR type F – Outlet : thread 9/16" UNF M.
000094034	Pressure regulator Easycare for O2 15 LPM – Inlet : AFNOR type F – Outlet : thread M12x1,25 M.
000094035	Pressure regulator Easycare10 O2 6 L/min. Inlet= AFNOR type F with outlet AFNOR
000094036	Pressure regulator Easycare10 O2 15 L/min. Inlet= AFNOR type F with outlet AFNOR
000094037	Pressure regulator Easycare10 AIR 15 L/min. Inlet= AFNOR type D with outlet AFNOR
000094040	Pressure regulator Easycare AIR 14 LPM with AFNOR Outlet - Inlet AFNOR type D - Outlet connection M12X1,25 with hose connector and outlet type AFNOR
000094041	Pressure regulator Easycare for AIR 14 L/min. – Inlet: UNI 4410 – Outlet: thread ¼" ISO 3253 M.
000094042	Pressure regulator Easycare 10 AIR 15 LPM Inlet: BS 341 - Outlet:9/16"m. UNF M
000094043	Pressure regulator Easycare10 AIR 30 LPM Inlet=UNI 10751
000094044	Pressure regulator Easycare10 O2 15 L/min. Inlet=BS341 Outlet=9/16"M. UNF

Easycare Plus model list

Code	Description
000554000	Pressure regulator Easycare Plus O2 14 L/min. - Inlet=UNI 10751 - Outlet=1/4"-9/16"M
000554001	Pressure regulator Easycare Plus O2 15 L/min. Inlet=pin-index Outlet=1/4"-9/16"M
000554002	Pressure regulator Easycare Plus O2 14 L/min. Inlet =NFSE29656 Outlet =1/4-12X1.25
000554003	Pressure regulator Easycare Plus O2 15 L/min. Inlet =DIN477-1 Outlet =1/4"-9/16"
000554004	Pressure regulator Easycare Plus O2 15 L/min. Inlet =BS 341-2 Outlet =1/4"-9/16"
000554005	Pressure regulator Easycare Plus O2 15 L/min. Inlet =UNI 10751 Outlet =1/4"-9/16"M
000554006	Pressure regulator Easycare Plus O2 6 L/min inlet UNI 10751 Outlet 1/4" - 9/16" M.
000554007	Pressure regulator Easycare Plus O2 14 L/min inlet UNI 10751 Outlet hose connector 1/4" with UNI outlet
000554008	Pressure regulator Easycare Plus O2 14 L/min inlet UNI 10751 Outlet hose connector 1/4" with AFNOR outlet thread M12x1,25-1/4" M.
000554009	Pressure regulator Easycare Plus O2 15 L/m cylinder conn= CGA 540 Outlet= 9/16" UNF M
000554010	Pressure regulator Easycare Plus O2 30 l/min. - inlet: UNI 10751 Outlet: 1/4" - 9/16" M.

MIG model list

Code	Description
000091025	MIG pressure regulator for Air, Outlet=generic



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 - 24040 LEVATE (BG) - VIA DEL LINO 6

UNITA' 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 E' 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

26/01/2015

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
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