



FLOW METER S.p.A.
Capitale Sociale: € 234.000 int. versato
Sede legale: L.go Porta Nuova, 14 - 24100 Bergamo
Amministrazione e Stabilimenti: Via del Lino, 6 - 24040 LEVATE (Bg)
Tel. +39/035/594047 - Telefax +39/035/594821
<http://www.flowmeter.it> - email info@flowmeter.it
Codice fiscale e Partita IVA: 01737040160 -
C.C.I.A.A. Bergamo 233737
Iscritta al Tribunale di Bergamo -
Volume 29771 - Reg. Società 30722



Certificato n. 421



Certificato n. 10627

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 prescribed by Annex II of Directive 93/42/EEC.

FLOW METER S.p.A., with registered office address Largo Porta Nuova, 14 (BG) - I, headquarters and production site address Via del Lino, 6, 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 93/42/EEC on Medical Devices.

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.
2. The devices in question should be considered as belonging to Class II B, following rule 11 of Annex IX of the above mentioned Directive.
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, 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 738-1: Pressure regulators for use with medical gases - Part 1: Pressure regulators and pressure regulators with flow metering device;
 - UNI 10751: Pressure regulators for use with medical gases – Pressure regulators and pressure regulators with flow-metering devices for inlet connections for gas cylinders.
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 (certificate no. 421/1/CE/003, first issue of 01/07/1998, current issue of 13/06/2007 and valid up to 12/06/2012). This system, adopted for the design and manufacturing of all devices, is declared as conforming to standards ISO 9001:2000 (ref. Certificate no. 421, current issue of 05/07/2006) and ISO 13485:2004 (ref. Certificate no. 10627, current issue of 05/07/2006).
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.

This declaration of conformity content is confirmed at every placing on the market of a new device batch, manufactured since 20/07/2007. 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: 20/07/07 - Ed. / Is.: 02/2

Attachment 01 – List of models with codes to which this Declaration refers

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 1/4" 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 1/4" 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 1/4" F.
000090012	Pressure regulator FM for O2 – Inlet : UNI 4406 long type – U. G 1/4" 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 1/4" F.
000090033	Pressure regulator FM for O2 – Inlet : DIN 477 – U. G. 1/4" 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
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
000090050	Pressure regulator FM for N2O – Inlet : UNI 9097 – Outlet : hose connector
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
000091061	Pressure regulator FM for O2 – Inlet : U42041820 with flowmeter Rs 15 LPM 9/16" UNF and hose connector
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
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.
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
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
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
000130000	Pressure regulator FM for O2 – Inlet : UNI 4406 with flowmeter Rs 15 LPM and humidifier TR/200

000130001	Pressure regulator FM for O ₂ – Inlet : UNI 4406 long type - with flowmeter Rs 15 LPM and humidifier TR/200
000130010	Pressure regulator FM for O ₂ – Inlet : UNI 10751 with flowmeter Rs 15 LPM and humidifier TR/200
000130050	Pressure regulator FM for O ₂ – Inlet : UNI 4406 wuth flowmeter Rs 30 LPM and humidifier TR/200
000131000	Pressure regulator FM for O ₂ – Inlet : UNI 4406 with flowmeter Rs 15 LPM and humidifier MAK/500
000130060	Pressure regulator FM for O ₂ – Inlet : NF E 29-656 with flowmeter Rs 15 LPM ¼" 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
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
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
000132300	Pressure regulator FM for O ₂ – Inlet : DIN 477 with flowmeter Rs 15 LPM G ¼" and humidifier TR/200
930070113	Pressure regulator with double pressure gauge (special drilling) – for emergency trolley ALVE ALSS

MU model list

Code	Description
000090112	Pressure regulator MU for O ₂ – Inlet : UNI 4406 – 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 4406 – with radial manoflowmeter 9 LPM – Outlet : hose connector
000091033	Pressure regulator MU for O ₂ – Inlet : UNI 4406 – with axial manoflowmeter 9 LPM – Outlet : hose connector
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

EASYCARE model list

Code	Description
000094000	Pressure regulator EASYCARE for O ₂ 14 L/min. – Inlet : U42041820 – Outlet : thread ¼" ISO 3253 M.
000094010	Pressure regulator EASYCARE for O ₂ 30 L/min. – Inlet : U42041820 – Outlet : thread ¼" ISO 3253 M.
000094030	Pressure regulator EASYCARE O ₂ 15 LPM with AFNOR Outlet - Inlet AFNOR type F - Outlet connection M12X1,25 with hose connector
000094040	Pressure regulator EASYCARE AIR 15 LPM with AFNOR Outlet - Inlet AFNOR type D - Outlet connection M12X1,25 with hose connector

Attachment 03 – EC marking certificate issued by Notified Body



ISTITUTO DI CERTIFICAZIONE DELLA QUALITÀ
www.certiquality.it

ORGANISMO NOTIFICATO N° 0546
NOTIFIED BODY N° 0546

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

FLOW METER SPA

I – 24100 BERGAMO (BG) – LARGO PORTA NUOVA 14

UNITA' OPERATIVE
OPERATING SITES

I – 24040 LEVATE (BG) – VIA DEL LINO 6

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

Riduttori di pressione e riduttori di pressione con flussimetri
Pressure regulators and pressure regulators with flow-metering devices

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 II

is in compliance with the requirements of Council Directive 93/42/EEC, Annex

CERTIFICATO N.
CERTIFICATE N.

421//CE003

PRIMA EMISSIONE
FIRST ISSUE 01/07/1998

EMISSIONE CORRENTE
CURRENT ISSUE 13/06/2007

DATA DI SCADENZA
EXPIRY DATE 12/06/2012


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