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

UNI EN ISO 9001:2000 CERTIQUALITY SISTEMA DI GESTIONE QUALITÀ CERTIFICATO

Certificato n. 421

UNI EN ISO 13485:2004 CERTIQUALITY SISTEMA DI GESTIONE QUALITÀ CERTIFICATO

Certificato n. 10627

DECLARATION OF CONFORMITY FOR THE MEDICAL DEVICE FAMILY "FLOWMETER FOR ANAESTHESIA"

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 **"FLOWMETER FOR ANAESTHESIA"**, 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:

- ISO 5358 "Anaesthetic machines for use with humans".

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/I/CE/001, first issue of 25/07/1997, 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 13/06/2007. This declaration of conformity is valid until the certificate expiry date.

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: 13/06/07 - Ed. / Is.: 02/1

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

Code	Description
000152070	KFM1 two gases flowmeter
000152071	KFM2 two gases flowmeter
000152072	KFM3 three gases flowmeter
000152073	KFM4 two gases flowmeter
000152074	KFM5 three gases flowmeter
000152075	KFM6 four gases flowmeter
000152076	KFM12 two gases flowmeter
000152077	KFM13 three gases flowmeter
000152078	KFM14 two gases flowmeter
000152079	KFM15 three gases flowmeter
000152080	KFM16 four gases flowmeter
000152050	FM 2200 two gases flowmeter
000152450	FM 2500 three gases flowmeter
000152300	FM 2300 two gases flowmeter
000152651	FM 2800 three gases flowmeter
000152652	FM 2900 four gases flowmeter
000152060	FM 2200 two gases flowmeter with by-pass
000152400	FM 2500 three gases flowmeter with by-pass
000152310	FM 2300 two gases flowmeter with by-pass
000152650	FM 2800 three gases flowmeter with by-pass
000152653	FM 2900 four gases flowmeter with by-pass
000152649	FM 2800/E three gases flowmeter with by-pass
000000500	“O_2 Flush” by-pass device

Attachment 03 – EC marking certificate issued by Notified Body

PER UNA MIGLIORE QUALITÀ DELLA VITA

CERTIQUALITY

ISTITUTO DI CERTIFICAZIONE DELLA QUALITÀ
www.certiquality.it

ORGANISMO NOTIFICATO N° 0546

NOTIFIED BODY N° 0546

APPROVAZIONE DEL SISTEMA DI QUALITA' 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

Unità flussometrica per anestesia
Flowmeter for anaesthesia

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 CouncilDirective 93/42/EEC, Annex

CERTIFICATO N.
CERTIFICATE N. **421/I/CE001**

PRIMA EMISSIONE *FIRST ISSUE*	*25/07/1997*
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

Via Gaetano Giardino 4 - 20123 Milano - tel. 02.80691.71 - fax 02.86465295 - certiquality@certiquality.it - www.certiquality.it