

DECLARATION OF CONFORMITY FOR THE MEDICAL DEVICE FAMILY "HUMIDIFIERS FOR MEDICAL USE"

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.

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 "HUMIDIFIERS FOR MEDICAL USE", 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.

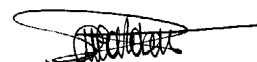
For this purpose it hereby guarantees and declares under its own responsibility that:

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, as stated in annex IX rule 2 of the above mentioned Directives.
3. The devices in question are sold in NON STERILE packaging.
4. The devices 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, 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 devices comply with all the requirements of the following standard:
 - EN ISO 8185 "Humidifiers for medical use – General requirements for humidification systems".
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 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 26/01/2015. 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: 26/01/2015 - Ed. / Is.: 03/1

Attachment 01 – List of models – Updated 26/01/2015

Code	Description
Series Lifeneb	
000029010	Lifeneb nebulizer for single patient use I. 9/16" UNF M.
000029011	Lifeneb nebulizer reusable I. 9/16" UNF M.
Series Mak	
000060000	Mak 500 humidifier I. 1/4" ISO 3253 F.
000060010	Mak 300 humidifier I. – U . Hose coupling – for AL cylinder
000060020	Mak 300 humidifier I. – U . Hose coupling – with basket for AL cylinder
000060030	Mak 500 humidifier I. 3/8" ISO 3253 F.
000060050	Mak 500 humidifier I. M12X1.25 F.
000060100	Mak 500 humidifier I. 9/16" UNF F.
000060101	Mak 300 humidifier I. 9/16" UNF F.
000060102	Mak 500 humidifier I. G. 1/2" F.
000060103	Mak 300 humidifier I. 1/4" ISO 3253 F.
000060104	Humidifier Mak/300 inlet: 3/8" ISO 3253 F
000060107	Mak 300 humidifier I. M12X1.25 F.
H00060000	Mak 500 humidifier I. 1/4" ISO 3253 F.
H00060100	Mak 500 humidifier I. 9/16" UNF F.
H00060101	Mak 300 humidifier I. 9/16" UNF F.
H00060112	Mak 500 humidifier I. 3/8" ISO 3253 F.
H00060113	Mak 300 humidifier I. 3/8" ISO 3253 F.
Series TR	
000070000	TR 200 humidifier I. 1/4" ISO 3253 F.
000070010	TR 200 humidifier I. 1/4" ISO - 3253 F. - metal lid
000070050	TR 200 humidifier I. 1/4" ISO - 3253 F. PSU

000070051	TR 200 humidifier I. 9/16" - UNF F PSU
000070052	Humidifier TR/200 PSU inlet: 3/8" ISO 3253 F
000070100	TR 200 humidifier I. 9/16" UNF F.
000070200	TR 200 humidifier I. M12X1.25 F.
000070201	TR 200 humidifier I. M12X1,25 F. PSU
000070202	TR 200 humidifier I. M12X1,25 F. metal lid
000070300	TR 200 humidifier I. 3/8" ISO 3253 F.
000070301	TR 200 humidifier I. 3/8" ISO 3253 F. PSU
Series Oxiter	
000075000	Oxiter humidifier I. 1/4" ISO 3253 F.
000075010	Oxiter humidifier I. 9/16" UNF F.
000075020	Oxiter 2 humidifier I. 1/4" ISO 3253 F. Vitalaire
000075025	Oxiter 2m humidifier I. 1/4" ISO 3253 F. Vitalaire
000075030	Oxiter humidifier I. 9/16" UNF F. Tecnocryo
000075100	Oxiter humidifier 200 Inlet 1/4" ISO 3253 F.
Series CH	
000080000	CH 200 humidifier I. 1/4" ISO 3253 F.
000080010	CH 200 humidifier I. G. 1/2" F.
000080020	CH 200 humidifier I. 3/8" ISO 3253 F.
000080050	CH 200 humidifier I. 9/16" UNF F.
000080100	CH 200 humidifier I. M12X1.25 F.
G00000008	CH 200 humidifier I. 3/8" ISO 3253 F.
G00000012	CH 200 humidifier I. 9/16" UNF F.
G00000032	CH 200 humidifier I. 3/8" ISO 3253 F. Rhonmed
G00000037	CH 200 humidifier I. 9/16" UNF F. Rhonmed
G00000047	CH 200 humidifier I. 3/8" ISO 3253 F. 596361



FLOW METER S.p.A.
Capitale Sociale: € 234.000 int. versato
Sede legale: Via del Lino, 6 - 24040 LEVATE (Bg)
Amministrazione e Stabilimenti: Via del Lino, 6 - 24040 LEVATE (Bg)
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<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



G00000052	CH 200 humidifier 325197626
H00060117	CH 200 humidifier inlet 9/16" UNF F HM008



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

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Mod. 5.20 LD 05 010205