MEDIMETER

Medimeter is a flowmeter intended for control and measurement of flow of air or oxygen administered to patients

MediMeter®
Flowmeter

EDITION 1/2011

ADVANTAGES

- Flat surface float allows easy and safe reading of flow values by the users
- Ergonomic desing, easy for cleaning
- Available with probe connector, rail mounting with a hose and twin versions
- Soft closing mechanism
- Resistant float against impact
- New scale - better reading of flow values

Technical Data

Gas pressure	O_2, air
Flow ranges	0 - 5 lpm
	0 - 15 lpm
	0 - 30 lpm
Inlet connection	according to national standard
Outlet connection	9/16" UNF, M12×1,25, G3/8,
	G 1/4 with hose nipple
Body material	Nickel-plated brass
O-rings	EPDM
Control knob	Polyamide
Body dimensions	Width 32 mm
	Height 160 mm
	Depth 60 mm
	Weight 280 g (without connector)
Temperature range:	
Storage	- 30 °C to + 60 °C
Operation	- 20 °C to + 60 °C
Regulatory status:	Complies with medical devices
	directive 93/42/EEC
	Complies with EN 15 002
	(Flow - matering devices for
	connection to terminal units of
	medical gas pipeline systems)
Classification:	Class IIa
Manufacturer:	GCE, s.r.o, Žižkova 381
	583 81 Chotěboř, CZ
CE - marking	CE0434

Accessories - HUMIDIFIERES

Art. Nr.	Description
K294432	MediWet 200 134°C G 3/8
K294416	MediWet 200 121°C G 3/8
K294402	MediWet 200 134°C G 9/16
K294401	MediWet 200 121°C G 9/16
K293498	MediWet 200 134°C 12 × 1,25
K293491	MediWet 200 134°C 12 × 1,25
K294452	MediWet 200 121°C G 1/4
K294435	MediWet 200 134°C G 1/4
K292254	MediWet 500 121°C M12 × 1,25

K294432

K292254

Gas Control Equipment

GCE world-wide: http://www.gcegroup.com

Art. Nr. 73510000525. Edition 1/2011. 07022011md © 2011

Traducere din limba engleză

MEDIMETER

Medimeter este un debitmetru destinat controlului şi măsurării debitului de aer sau oxigen administrat pacienţilor

Debitmetru MediMeter®

EDIŢIA 1/2011

AVANTAJE

- Suprafaţa plată a flotorului permite o citire uşoară şi sigură a valorilor debitului de către utilizatori
- Design ergonomic, uşor de curăţat
- Disponibil cu conector tată, cu montare pe şină şi furtun şi versiune dublă
- Mecanism de închidere uşor
- Flotor rezistent la impact
- Scală nouă - citire mai bună a valorilor de debit

Traducere din limba engleză

Date tehnice

Presiune gaz	O_2, aer
Game de debit	0 - 5 lpm 0 - 15 lpm 0 - 30 lpm
Conexiune intrare	conform standardului naţional
Conexiune ieşire	9/16” UNF, M12×1,25, G3/8, G 1/4 cu ştuţ furtun
Materialul corpului	Alamă nichelată
Garnituri inelare	EPDM
Buton de comandă	Poliamidă
Dimensiuni corp	Lăţime 32 mm Înălţime 160 mm Adâncime 60 mm Greutate 280 g (fără conector)
Gamă de temperatură:	
Depozitare	între - 30°C şi + 60°C
Funcţionare	între - 20°C şi + 60°C
Reglementări:	În conformitate cu directiva 93/42/CEE privind dispozitivele medicale În conformitate cu EN 15 002 (Dispozitive de măsurare a debitului pentru conectarea la prizele sistemelor de alimentare cu gaz medical)
Clasificare:	Clasa IIa
Producător:	GCE, s.r.o, Ž ižkova 381 583 81 Chotěboř, CZ
Marcaj CE	CE0434

Accesorii - UMIDIFICATOARE

Nr. art.	Descriere
K294432	MediWet 200 134°C G 3/8
K294416	MediWet 200 121°C G 3/8
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K294435	MediWet 200 134°C G 1/4
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K294432

K292254

Gas Control Equipment

GCE la nivel global: http://www.gcegroup.com

Nr. art. 73510000525. Ediţia 1/2011 07022011md © 2011

Subsemnata **ŞTEFANA FORGACIU**, traducător autorizat de M. J. cu nr. **37629**, certific exactitatea traducerii în limba română, cu textul înscrisului în copie, în limba engleză.

TRADUCĂTOR **ŞTEFANA FORGACIU** - *AUTORIZAT* cu nr. **37629**

EC Certificate
Full Quality Assurance System

A DNV GL & NEMKO COMPANY

Certificate No.:	Project No.:	Valid Until:
10401-2017-CE-CZS-NA-PS Rev. 0.0	**PRJC-189266-2009-PRC-CZE**	**30 MARCH 2020**

This is to certify that the quality system of:

GCE s.r.o.
Žižkova 381
583 01 Chotěboř
Czech Republic

For design, production and final product inspection/testing of:

Medical Devices for use with Medical Gases

Has been assessed with respect to:

The conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H2) of Council Directive 93/42/EEC on Medical Devices, as amended

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and Date:
Høvik, 1 November 2017

NORWEGIAN ACCREDITATION
PROD 021
Notified Body No.: 2460

For:
DNV GL-NEMKO PRESAFE AS

Alessandra Rinna

The Certificate has been digitally signed.
See www.presafe.com/digital_signatures for more info

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.

EC Certificate
Full Quality Assurance System

Certificate No.: **10401-2017-CE-CZS-NA-PS Rev. 0.0**
Project No.: **PRJC-189266-2009-PRC-CZE**
Valid Until: **30 MARCH 2020**

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift for Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0	Supersedes DNV GL (NB0434) certificate No. 73547-2010-CE-CZS-NA 7.0 following transfer of notified body function to DNV Nemko Presafe AS (NB2460)	2017-11-01

Products covered by this Certificate:

Product Description	Product Name	Class
Medical devices for use with Medical Gases	Pressure regulators integrated with cylinder valves	IIb
	Cylinder valves	
	High Pressure Regulators	
	Terminal Unit	
	Ambulance Panel	
	Central gas supply system	
	Resuscitator	
	Adjustable regulators	
Medical devices for use with Medical Gases	Flow-metering devices (Ball flow meters, Flow selectors)	IIa
	Humidifiers	
	Low pressure hoses	
	Low pressure regulators	
	Terminal Unit (for Anesthetic Gas Scavenging System)	
	Suction equipment (Suction ejectors, Vacuum regulators)	
	Demand Valve	
	Gas Switch	
	Gas Saver	

The complete list of devices is filed with the Notified Body

EC Certificate
Full Quality Assurance System

A DNV GL & NEMKO COMPANY

Certificate No.:	Project No.:	Valid Until:
10401-2017-CE-CZS-NA-PS Rev. 0.0	**PRJC-189266-2009-PRC-CZE**	**30 MARCH 2020**

Sites covered by this certificate

Site Name	Address
GCE s.r.o.	Žižkova 381, 583 01 Chotěboř, Czech Republic

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

DECLARATION OF CONFORMITY

for CE – marking according to Annex II of Medical Devices Directive 93/42/EEC

Manufacturer*:* **GCE s.r.o.**
Žižkova 381
583 81 Chotěboř
CZECH REPUBLIC

The GCE s.r.o. herewith declares under his sole responsibility that the product

Product name:	Flow-metering devices
Model:	Mediflow + Mediflow II Medimeter MC315
Risk Classification:	IIa

is in conformity with applicable regulation

Directive:	MDD 93/42/EC, Annex II – 2007/47EC Amending
Quality Assurance Standards:	EN ISO 9001:2008 EN ISO 13485:2012
Procedural Standards:	EN ISO 15002-1:2006 EN 980:2008 EN ISO 14971:2012 EN 1041:2008

Product is in compliance with the requirements of Annex II the MDD 93/42/EEC and is safe for to be declared using in standard conditions.
Any modification to the product, not authorized by us, will invalidate this declaration.

EC Certificate No. 73547-2010-CE-CZS-NA 6.0 issued by by Det Norska Veritas, Veritasveien 1, 1322 Høvik, Norway, Notified Body No. 0434.

Date of Issue: 2015-09-01
Place of Issue: Chotěboř

Signature:
Quality Engineer: Vít Leszkow

GCE, s.r.o. Tel. 00 420 569 661 111 E-mail: gce@gcegroup.com
Žižkova 381 Fax. 00 420 569 661 138 http:// www.gcegroup.com
583 81 Chotěboř
Czech Republic VAT number: CZ27110991