



The Mediwet humidifiers are developed for oxygen therapy at hospital or at home. This type of equipment is indispensable to prevent dehydration of the mucous membranes when inhaling oxygen during an extended period of time, or at large flows. It is intended to be connected to the outlet of a wall flowmeter, a regulator flowmeter, or an oxygen concentrator.

Humidifiers Mediwet

EDITION 1/2009

The reusable humidifier is ergonomic, comfortable, economic, and easy to maintain:

- Reduced dimensions and weight.
- Silent thanks to a high performance diffuser.
- All components, except the diffuser, are reusable for minimum 20 autoclave cycles.
- Improved adaptation to the needs and possibilities of the user with two autoclave possibilities, depending on the material.
- Fast to assemble/disassemble.

MEDIWET 2 HUMIDIFIER

Art. No.	Denomination
K293498	Mediwet 2 134 °C inlet connection M12x1,25F
K294402	Mediwet 2 134 °C inlet connection UNF 9/16 F
K293491	Mediwet 2 121 °C inlet connection M12x1,25 F
K294401	Mediwet 2 121 °C inlet connection UNF 9/16 F
K294416	Mediwet 2 121 °C inlet connection G3/8F

Spare Parts

Art. No.	Denomination
K301062	Jar 134 °C
K301059	Jar 121 °C
K301063	Lid 134 °C connection M12x1,25
K301060	Lid 121 °C connection M12x1,25
K301064	Lid 134 °C connection 9/16
K301061	Lid 121 °C connection 9/16
K301078	Lid 134 °C connection G3/8
K301079	Lid 121 °C connection G3/8
K294404	Inlet connection gasket M12x1,25, 10 pcs
K294407	Inlet connection gasket 9/16, 10 pcs
K294433	Inlet connection gasket G3/8, 10 pcs
K294409	Bottle gasket 134 °C, 10 pcs
K294408	Bottle gasket 121 °C, 10 pcs

Consumables

Art. No.	Denomination
K294415	Diffuser, 10 pcs
M401006	Silicone hose 1 m
K294486	Silicone tube, 10 pcs
K294434	Complete diffuser (tube 13 cm and diffuser, 10 pcs)

MEDIWET HUMIDIFIER

Art. No.	Denomination
K292247	Mediwet 200 ml
K292254	Mediwet 500 ml

Spare Parts

Art. No.	Denomination
K308031	Inlet gasket
K308035	Jar gasket
K301047	Lid
K291576	Diffuser tube
K291582	Jar 200 ml
K301091	Jar 500 ml


K293498

K293491
Technical Data - MEDIWET 2 HUMIDIFIER

Contents:	Only sterile water
Dimensions:	Height 190 x 67 Width (incl hose nipple) x 57Ø mm
Weight:	Polycarbonate version 75 g Polysulphone version 115 g
Capacity:	200 ml of water
Consumption:	8 ml of water per hour at a as flow of 10 l/min at 20 °C
Material:	Jar autoclavable at 121 °C: polycarbonate Jar autoclavable at 134 °C: polysulphone Lid and outlet hose nipple: polypropylene Inlet nut: Chromed brass Diffuser: Polyethylene Hose, flat gasket: Silicone Toric gasket: Ethylene propylene
Outlet connection	Tapered hose nipple for hose 6x9 mm (recommended length 2 m)
Cleaning:	Water, non abrasive detergent. Never use solvents.
Disinfection:	An alcoholic solution, or other solution compatible with the material according to the disinfectant manufacturer.
Autoclave:	Polycarbonate version 121 °C for 30 minutes Polysulphone version 134 °C for 18 minutes
Special case:	Diffuser: exchange at every cleaning - do not sterilise! Silicone tube: autoclave at 121 °C (if cold disinfection please exchange!)
Maintenance	Check that the humidifier is whole and air tight before use. Monthly exchange of gaskets is recommended. Exchange the diffuser when its microperforations no longer exist.
Durability	Minimum 20 autoclave cycles under the condition that all instructions accompanying the product are adhered.

Technical Data - MEDIWET HUMIDIFIER

Contents:	Only sterile water
Dimensions:	200 ml: Height 115 x Width 83 (incl hose nipple) x 57Ø mm 500 ml: Height 210 x Width 89 (incl hose nipple) x 70Ø mm
Weight:	200 ml: 185 g 500 ml: 190 g
Material:	Jar and lid: polycarbonate Connections: chromed brass

Recycling

The product shall be recycled according to local regulations.


K292254

K292247



Umidificatoarele Mediwet au fost dezvoltate pentru terapia cu oxigen în spital sau la domiciliu. Acest tip de echipament este indispensabil pentru a preveni deshidratarea membranelor mucoase atunci când se inhalează oxigen de-a lungul unei perioade de tip prelungite sau în debite mari. Acesta trebuie conectat la priza unui debitmetru de perete, un debitmetru cu regulator sau un concentrator de oxigen.

Umidificatoare Mediwet

EDIȚIA 1/2009

Umidificatorul reutilizabil este ergonomic, confortabil, economic și ușor de întreținut:

- Dimensiuni și greutate reduse.
- Silențios datorită difuzorului de înaltă performanță.
- Toate componentele, cu excepția difuzorului, pot fi reutilizate timp de minimum 20 de cicluri în autoclavă.
- Adaptare îmbunătățită la nevoile și posibilitățile utilizatorului cu două posibilități de autoclavă, în funcție de material.
- Ușor de asamblat/dezasamblat.

UMIDIFICATOR MEDIWET 2

Nr. art.	Denumire
K293498	Conexiune internă 134°C Mediwet 2 M12x1,25F
K294402	Conexiune internă 134°C Mediwet 2 UNF 9/16 F
K293491	Conexiune internă 121°C Mediwet 2 M12x1,25 F
K294401	Conexiune internă 121°C Mediwet 2 UNF 9/16 F
K294416	Conexiune internă 121°C Mediwet 2 G3/8F

Piese de schimb

Nr. art.	Denumire
K301062	Borcan 134°C
K301059	Borcan 121°C
K301063	Capac 134°C conexiune M12x1,25
K301060	Capac 121°C conexiune M12x1,25
K301064	Capac 134°C conexiune 9/16
K301061	Capac 121°C conexiune 9/16
K301078	Capac 134°C conexiune G3/8
K301079	Capac 121°C conexiune G3/8
K294404	Manșon conexiune internă M12x1,25, 10 buc.
K294407	Manșon conexiune internă 9/16, 10 buc.
K294433	Manșon conexiune internă G3/8, 10 buc.
K294409	Manșon sticlă 134°C, 10 buc.
K294408	Manșon sticlă 121°C, 10 buc.

Consumabile

Nr. art.	Denumire
K294415	Difuzor, 10 buc.
M401006	Furtun din silicon 1 m
K294486	Tub din silicon, 10 buc.
K294434	Difuzor complet (tub 13 cm și difuzor, 10 buc.)

UMIDIFICATOR MEDIWET

Nr. art.	Denumire
K292254	Mediwet 200 ml
K292254	Mediwet 500 ml

Piese de schimb

Nr. art.	Denumire
K308031	Manșon intern
K308035	Manșon borcan
K301047	Capac
K291576	Tub difuzor
K291582	Borcan 200 ml
K301091	Borcan 500 ml



K293498



K293491

Date tehnice - UMIDIFICATOR MEDIWET 2

Conținut:	Numai apă sterilă
Dimensiuni:	Înălțime 190 x 67 Lățime (incl. ștuț furtun) x 57Ø mm
Greutate:	Versiune policarbonat 75 g Versiune polisulfon 115 g
Capacitate:	200 ml apă
Consum:	8 ml apă pe oră la un debit de 10 l/min la 20°C
Material:	Borcan autoclavabil la 121°C: policarbonat Borcan autoclavabil la 134°C: polisulfon Capac și ștuț furtun de ieșire: polipropilenă Piuliță de intrare: Alamă cromată Difuzor: Polietilenă Furtun, manșon plat: Silicon Manșon toric: Etilenă propilenă
Conexiune de ieșire	Ștuț furtun conic pentru furtun 6x9 mm (lungime recomandată 2 m)
Curățare:	Apă, detergent neabraziv. Nu utilizați niciodată solvenți.
Dezinfecție:	Soluție cu alcool sau altă soluție compatibilă cu materialul în conformitate cu producătorul dezinfectantului.
Autoclavă:	Versiune policarbonat versiune 121°C timp de 30 minute Versiune polisulfon 134°C timp de 18 min.
Cutie specială:	Difuzor: a se schimba la fiecare curățare – a nu se steriliza! Tub de silicon: autoclavă la 121°C (în caz de dezinfecție la rece, vă rugăm să o schimbați!)
Întreținere	Verificați ca umidificatorul să fie întreg și etanș înainte de utilizare. Se recomandă schimbarea lunară a manșoanelor. Schimbați difuzorul atunci când nu mai există microperforații.
Durabilitate	Minimum 20 cicluri în autoclavă cu condiția ca toate instrucțiunile care însoțesc produsul să fie respectate.

Date tehnice - UMIDIFICATOR MEDIWET

Conținut:	Numai apă sterilă
Dimensiuni:	200 ml: Înălțime 115 x lățime 83 (inclusiv ștuț furtun) x 57Ø mm 500 ml: Înălțime 210 x lățime 89 (inclusiv ștuț furtun) x 70Ø mm
Greutate:	200 ml: 185 g 500 ml: 190 g
Material:	Borcan și capac: policarbonat Conexiuni: alamă cromată

Reciclare

Produsul va fi reciclat în conformitate cu reglementările locale.



Gas Control Equipment



K292254



K292247

GCE Norden AB, Flygfältsvägen 1, Box 21044,
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Fax: +46 (0) 40 38 83 50
<http://www.gcegroup.com>

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

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



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

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



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	
Medical devices for use with Medical Gases	Adjustable regulators	IIa
	Flow-metering devices (Ball flow meters, Flow selectors)	
	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

Certificate No.:
10401-2017-CE-CZS-NA-PS Rev. 0.0

Project No.:
PRJC-189266-2009-PRC-CZE

Valid Until:
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 -
2007/47EC Amending

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: Humidifiers

Model : MEDIWET

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 8185:2009 EN ISO 15223-1:2012
EN ISO 14971:2012 EN 1041:2008

**Product is in compliance with the requirements of Annex I the MDD 93/42/EEC - 2007/47EC
Amending 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 Norske Veritas,
Veritasveien 1, 1322 Høvik, Norway, Notified Body No. 0434**

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

Signature: 
Quality Engineer: Vit Leszkow