CERTIFICATE

EC Certificate

Full Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-21-817

We hereby declare that an examination of the under mentioned full quality assurance system has been carried out following the requirements of the national legislation to which the undersigned is subjected, transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on medical devices. We certify that the full quality assurance system conforms with the relevant provisions of the aforementioned directive.

Organization:

ÇAĞDAŞ ELEKTRONİK MEDİKAL SİSTEMLER SANAYİ TİCARET LİMİTED ŞİRKETİ

DEFTERDAR MAH. KERESTECİLER SİT. HACIBİLGİN SK. NO: 16
EYÜP / İSTANBUL / TURKEY

Products: Bed Head Unit, Intensive Care Unit, Wall Gas Module, Oxygen Plant/ Manifold System, Nistrousoxide Plant/Central, Medical Gas Outlet And Gas Probes, Vacuum/Suction Regulator, Compressed Air Pressure Regulator, Oxygen Pressure Regulator, Oxygen Therapy Devices, Oxygen Flowmeter

The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number: M.6003.01
Expiry Date: 27 May 2024

Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

Muhteşem Gökhan Yücel
Head of Notified Body

20 May 2021, Istanbul, Turkey

Digitally signed by Jighili Tatiana
Date: 2021.07.23 19:11:20 EEST
Reason: MoldSign Signature
Location: Moldova

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cad. No:15 Tepeören, Tuzla, Istanbul, Turkey
Tel.: +90 216 593 25 75 , Fax: +90 216 593 25 74
Web: www.kiwa.com.tr , e-mail: posta@kiwa.com.tr

CERTIFICATE

ÇAĞDAŞ ELEKTRONİK MEDİKAL SİSTEMLER SANAYİ VE TİCARET LİMİTED ŞİRKETİ

DEFTERDAR MAH. KERESTECİLER SİT. HACIBİLGİN SK. NO: 16 EYÜP - İSTANBUL - TURKEY

with a scope of

MEDICAL GAS SYSTEMS DESIGN, PRODUCTION, DISTRIBUTION, INSTALLATION AND TECHNICAL SERVICE

ISO 9001:2015

Has established a quality management system in accordance with international standard.

" Following elements of the standard are excluded "

" None "

Certificate No	: M 11615
Initial Certification Date	: 20 May 2021
Certification Date	: 20 May 2021
Expiration Date	: 19 May 2024

General Manager

Kiwa Belgelendirme Hizmetleri A.Ş.
ITOSB 9. Cadde No. 15 Tepeören Tuzla
Istanbul / Turkey

Tel: + 90 216 593 25 75
Faks: + 90 216 593 25 74
info@kiwa.com.tr
www.kiwa.com.tr

Certificate is valid till expiration date, subject to successful completion of periodical surveillance audits.
Please contact above numbers for detailed information.

Kalite Yönetim Sistemi
TS EN ISO/IEC 17021-1
AB-0006-YS

TÜRKAK BDS NO
YS-870D-D81C

Last Modified : 20 May 2021 - R 00

CERTIFICATE

ÇAĞDAŞ ELEKTRONİK MEDİKAL SİSTEMLER SANAYİ VE TİCARET LİMİTED ŞİRKETİ

DEFTERDAR MAH. KERESTECİLER SİT. HACIBİLGİN SK. NO: 16 EYÜP - İSTANBUL - TURKEY

MEDICAL GAS SYSTEMS DESIGN, PRODUCTION, DISTRIBUTION, INSTALLATION AND TECHNICAL SERVICE

with a scope of

EN ISO 13485:2016

Has established a management system in accordance with international Medical Devices Quality Management System Standard

"Following elements of the standard are excluded"
"7.5.5" "7.5.7" "7.5.9.2"

Certificate No	: M 11616
Initial Certification Date	: 20 May 2021
Certification Date	: 20 May 2021
Expiration Date	: 19 May 2024

Kiwa Belgelendirme Hizmetleri A.Ş.
ITOSB 9. Cadde No. 15 Tepeören Tuzla
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General Manager

Certificate is valid till expiration date, subject to successful completion of periodical surveillance audits.
Please contact above numbers for detailed information.

TÜRKAK BDS NO
YS-A711-1EF8

Last Modified: 20 May 2021 - R 00

ÇAĞDAŞ
MEDİKAL

OXYGEN FLOWMETERS DIN/BS/FR STANDARDS

- Complete Metal Body
- Humidifier bottle connection consists of aluminum material
- Central system connection probe available
- Resistant to 121° sterilization

Degree protective cover consists of polycarbonate material

Technical Details:

Inlet : Whitworth GAS 1/8"
Outlet: DISS O2 9/16" - 18 UNF
Pressure: 4.2 Kg/cm2 – 60 psi – 414 kPa - 4.14 Bar
L/min: 0 - 15

DIN STD.

AFNOR STD.

BS STD.

DIN STD: GE 05 1001
AFNOR STD: GE 05 2001
BS STD: GE 05 3001

THEME: 'HUMAN LIFE'

www.cagdasmedikal.com / cagdas@cagdasmedikal.com

ÇAĞDAŞ MEDİKAL	**DECLARATION OF CONFORMITY**	Section No	TD-06/5.2
		Rev. Date	28.05.2021
		Rev. No	02
		Page No	1 / 1

Company Name:

ÇAĞDAŞ ELEKTRONİK MEDİKAL SİSTEMLER SANAYİ VE TİCARET LTD. ŞTİ.

Address : Defterdar mah. Keresteciler Sitesi Hacı Bilgin Sok. No:16 Eyüp

City : İSTANBUL

Country : TÜRKİYE

Tel : +90 212 613 70 73

Web : www.cagdasmedikal.com

Product Name : Oxygen Flowmeter, Oxygen Therapy Devices

Model Code : GE 05 1001, GE 05 2001, GE 05 3001, GE 06 0101, GE 06 0102, GE 06 0103, GE 05 1000, GE 05 2000, GE 05 3000, GE 07 0300, GE 07 0301, GE 07 0302.
GE 05 5000, GE 05 5001, GE 05 5002.

GMDN Code : 61365, 61364

Class and Rule : Class IIb Rule 11

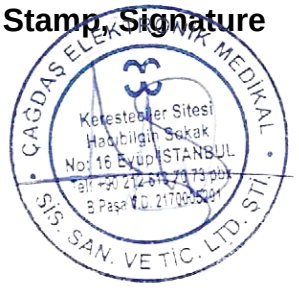
Conformity Assessment Procedure: Annex II (Section 4 excluded)

Applicaple Standarts: EN ISO 13485:2016, EN ISO 14971:2012, EN ISO 15223-1:2016, EN 1041:2008 + A1:2013, EN 62366-1:2015/A1:2020, EN ISO 10524-1:2019, EN ISO 15002:2008/A1:2019, EN ISO 15001:2011

We herewith declare on our own responsibility that the above mentioned meet the provisions of the Council Directive 93/42/EEC with amended directive 2007/47/EC for Medical Device Directive.

Notified Body : KIWA Belgelendirme Hizmetleri A.Ş.
NB Address : ITOSB 9. Cadde No: 15 Tepeören Tuzla İstanbul TÜRKİYE
NB Identification Number : 1984
EC Certificate Number : 1984-MDD-21-817
EC Certificate Valid Date : 27 May 2024

Stamp, Signature



City, Date : **İstanbul, 28.05.2021**

Name : **Deniz Kurtuluş**

Position : **General Manager**

Oxygen Flowmeters

User Manual

Oxygen Flowmeter – DIN Std.

Oxygen Flowmeter – FR Std.

Oxygen Flowmeter – BS Std.

Double Oxygen Flowmeter

GE 05 Series

Çağdaş Elektronik Medikal Sistemler San. Ve Tic. Ltd. Şti

CONTENTS

1. GENERAL INFORMATION

Copyright

Declaration of Conformity to CE

These devices are "Flow Measuring Devices for Connection to End Units of Medical Gas Pipeline Systems" TS EN ISO 15002, "Pressure Regulators for Oxygen and Nitrogen Monoxide Medical Gases "TS EN ISO 10524-1, "Pressure regulators - For medical gases - part 1: Pressure regulators and pressure regulators with flow meter",“Medical gas piping systems - Part 1: Piping systems for compressed medical gases and vacuum” comply with the requirements specified in TS EN ISO 7396-1 and MDD / 93/42 / EEC Medical Devices Directive.

Notified Body Information

Title : Kiwa Belgelendirme Hizmetleri A.Ş.

Tel. : +90 (216) 593 25 75

Fax : +90 (216) 593 25 74

E-mail: posta@kiwa.com

Warranty Period

ÇAĞDAŞ Flowmeter is guaranteed for 2 (two) years, including all parts, against material, workmanship and manufacturing defects, provided that it is used as shown in the user manual.

The following situations are excluded from warranty:

1. Damages and failures caused by misuse

2. Damages and failures during loading, unloading and transportation after the product is delivered to the customer

3. Malfunctions caused by the use of the product contrary to the matters stated in the user manuals

Expected life of the item

The expected life of the device as determined by the Ministry of Science, Industry and Technology is 10 years

2. INTRODUCTION

Thank you for purchasing ÇAĞDAŞ brand Flowmeter. Our product has been carefully designed and manufactured to provide you with the best quality and performance. Please carefully read all the information regarding the operation and safety of this device and keep this manual as a reference.

This manual describes the installation, usage and cleaning steps for the ÇAĞDAŞ brand Flowmeters.

Considerations During Transportation and Transportation

Please follow the instructions on the device boxes during transportation.

Maintenance and Repair Considerations

In cases that require maintenance and repair, please call the authorized service of the device.

Connection and Mounting Information

Please refer to the following sections for connection and assembly information.

3. SECURITY

To ensure the safety of the flowmeter and the user and to be used and maintained:

• Before putting the flowmeter into service, make sure that this user manual is read and understood with warnings and explanations.
• The purchaser is responsible for ensuring that the personnel responsible for the use or maintenance of the flowmeter learn about the contents of this user manual.
• Keep the user manual at a place where the personnel responsible for the use and maintenance of the Flowmeter can reach.
• Do not use the flowmeter for purposes other than described in this manual.
• ÇAĞDAŞ reserves the right to change and / or remove the technical specifications of the device and the information contained in this manual.
NOTE:
• This manual can be used for the models are GE 05 1001, GE 05 2001, GE 05 3001, GE 06 0101, GE 06 0102, GE 06 0103, GE 05 1000, GE 05 2000, GE 05 3000, GE 07 0300, GE 07 0301, GE 07 0302, GE 06 1002, GE 06 2002 GE 06 3002, GE 05 0002, GE 05 0002-1, GE 05 0008, GE 05 0008 - 1 , GE 09 1000, GE 05 5000 GE 05 5001, GE 05 5002, GE 05 6000, GE 05 6001, GE 05 7001, GE 05 8001 .

ATTENTION!

Follow the warnings and instructions in the user manual. It should only be used by authorized personnel.

3.1 Symbols and Descriptions

Symbol	Description	Symbol	Description
	Not Sterile		It is not household waste
	Attention! Consult the accompanying documents		Do not reverse
	Look at the user manual		Keep Dry
	AP Category device according to IEC 601		Attention! Frangible!
	Manufacturer		No Oil
	Do not use damaged packages		Compliant with MDD 93/42/ EEC Medical devices directive
	Production date		

3.2 Device Label

ATTENTION!

- ✓ The device label should not be tampered with or changed, and the label should not be removed.

4. PACKAGING, TRANSPORT AND STORAGE

4.1. Physical Environment

- ✓ Ambient temperature : 0C ~ +50C
- ✓ Humidity : %40

4.2. Transport Conditions

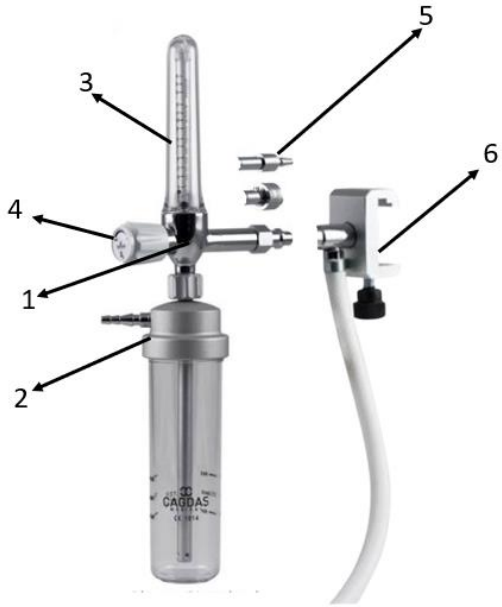
• Please follow the instructions on the device boxes during transportation and transportation.

• Matters Related to Maintenance and Repair In cases that require maintenance and repair, please call the authorized service of the device.

• Information on Connection and Mounting Please refer to the following sections for connection and assembly information.

5. PRESENTATION

5.1. Device and Part Introductions



OXYGEN FLOWMETERS			
PART NO	PART NAME	PART NO	PART NAME
1	**Chassis**	4	**Hand Adjusting Valve**
2	**Humidifier Bottle**	5	**Gas Outlets Probes**
3	**Degree Tube**	6	**Rail Mounting Apparatus**

6. TROUBLESHOOTING

Breakdown	Reasons	Solutions
Oxygen Not Coming	There is no oxygen in the system	Check the oxygen cylinders
	Flowmeter is not plugged in	Make sure the flowmeter is plugged into the socket
	Does not tighten the humidifying bottle gasket	Make sure the humidifying bottle is tightened
The on-off switch does not work	The on-off switch is defective	Call the authorized service

7. TECHNICAL SPECIFICATIONS

Specifications	Flowmetre
Measuring range	0-15 l/min (Adult) – 0-7 l/min (Pediatric)
Outlet size	9/16”
Chassis	Chrome Plated Brass Body
On-Off	Precision Adjusted On-Off
Height	150 mm
Width	120 mm (Normal probe type) – 150 mm (Long probe type)
Depth	33 mm
Weight	329 g (Normal probe type) – 382 g (Long probe type)

8. INSTALLATION AND USE OF THE DEVICE

Flow adjustment screw of the flowmeter is connected to a medical gas outlet conforming to the standard when in closed position. The humidifying chamber is removed by turning it counterclockwise. Approximately 50ml of pure water is put into the humidification chamber. The humidification chamber is attached to the flowmeter by turning it clockwise. Nose glasses going to the patient are attached to the outlet hose holder. Flow of the flow meter is adjusted by turning the adjustment screw counter clockwise. The flow of gas is monitored from the flow indicator and gas flow adjustment is made according to the flow indicator. When the flowmeter is not used, the flow adjustment screw is turned clockwise and turned off.

FLOWMETER ACCESSORIES

1. Gas-Specific Jack: It is a probe that is connected to the medical gas socket of the flowmeter and enables the entry of medical gas and is designed and manufactured in a way that it cannot be connected to other medical gas outlets in order to prevent life-threatening.

2. Flow Adjustment Screw: It is the button used to adjust the amount of medical gas entering the flow meter through the medical gas sockets according to the time during the delivery to the patient.

3. Flow Indicator: It is a plastic tube that shows the flow rate of humidified medical gas, oxygen or medical air in l/min from the flowmeter to the patient, and the measurement divisions on it are used to adjust the flow rate of the said medical gases.

4. Humidification container: It is a rigid plastic chamber that provides information to the user about the amount of pure water through the divisions on it and can be sterilized in a 134 ° C autoclave, which provides humidification of the medical gas, oxygen or medical air entering the flow meter from the medical gas sockets.

5. Outlet Hose: It is the piece with an external profile to which the hose is connected in order to deliver the medical gas, oxygen or medical air passing through the humidification chamber of the flowmeter to the patient, which will make the hose connection easy and prevent the hose from coming out by itself.

ATTENTION ! The flowmeter should be renewed every time the water is outed in the flowmeter!...

8.1. PERFORMANCE CONTROL, SIDE EFFECTS AND CALIBRATION INFORMATION

Check the tightness between the flowmeter and the medical gas outlet. Check whether there is any leakage in the flowmeter device. These checks should be made every time the flowmeter is attached and disconnected from the medical gas outlet.

Calibration Frequency

In order for the flowmeter to measure precisely, it should be calibrated at least once a year according to the frequency of use.

Performance Check

1. Flowmeter should not have more than 20% deviation in full scale.

2. The flowmeter should be connected to the central gas system and it should be observed whether there is a leak when the outlet is closed.

Side effects

Since the flowmeter is not a device that provides direct drug delivery to the patient and the material used is compatible with oxygen, it has no side effects.

9. CLEANING AND RECYCLING

9.1 Cleaning of Flowmeter

Wipe the surface of the flowmeter using natural soap and a soft cloth and dry. Make sure that the surface of the devices is dry before use.

After each use, the humidification cup of the flowmeter should be sterilized by autoclave at 134 ° C.

9.2. Recycling

If you are going to destroy the flowmeter or replace any part, check the recyclability of each part. Follow the recycling procedure to the flowmeter. If you would like to learn more about recycling, please contact the relevant institutions and facilities or visit the websites that provide information about recycling on the internet.

10. AUTHORİZED SERVICES

ÇAĞDAŞ ELEKTRONİK MEDİKAL SİSTEMLER SAN. TİC. LTD. ŞTİ

İstanbul - Eyüp / Factory

Address : 34050 Defterdar Neighborhood, Hacı Bilgin Street No: 16 EYÜP/İSTANBUL

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