

# CERTIFICATO N° 306SGQ06

CERTIFICATE N° 306SGQ06

Si certifica che il  
*this is to certify that - on certifie que*

## Sistema di Gestione per la Qualità

*Quality Management System - Système de Gestion pour la Qualité*

messo in atto da  
*implemented by - mis en acte par*

**MD S.r.l**

Via Guido Rossa, 22/c - IT 30037 SCORZE' (VE)

nella Sede Operativa di  
*Operative Unit - Siège Opérationnel*

Via Guido Rossa, 22/c - IT 30037 SCORZE' (VE)

è conforme alla norma  
*is in compliance with the standard - est conforme à la norme*

**UNI EN ISO 9001-2015 (ISO 9001-2015)**

per i seguenti Processi  
*concerning the following kinds of Processes - pour les suivants Processus*

**Progettazione e produzione di componenti per impianti di distribuzione  
dei gas medicinali e per vuoto e per impianti di evacuazione dei gas anestetici.**

*Design and manufacture of components for pipeline systems for compressed medical gases  
and vacuum and for anaesthetic gas scavenging disposal systems.*

*Conception et fabrication de composants pour systèmes de distribution de gaz médicaux comprimés  
et de vide e pour Systèmes d'évacuation de gaz d'anesthésie non réutilisables*

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la Certificazione in vigore applicabili  
*This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable*

*Ce certificat est soumis à la conformité avec les termes et conditions du règlement de certification applicable.*

In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana  
*In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language*

*En cas de divergence entre les langues utilisées pour la traduction du contenu de ce certificat, veuillez vous référer à la langue italienne*

L'AMMINISTRATORE DELEGATO

MANAGING DIRECTOR



Dr. Ing. Roberto Cusolito

Data di Prima Emissione

*Forst Issue Date*

2011-10-10

Data di Rinnovo

*Renewal Date*

2020-11-19

Data di Scadenza

*Expiration Date*

2023-06-05

Settore IAF 17



SGQ N° 023A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC  
*Signatory of EA, IAF and ILAC Mutual Recognition Agreements*



# CERTIFICATO N° 306DM09

CERTIFICATE N° 306DM09

Si certifica che il  
*this is to certify that - on certifie que*

## Sistema di Gestione per la Qualità

*Quality Management System - Système de Gestion pour la Qualité*

messso in atto da  
*implemented by - mis en acte par*

**MD S.r.l**

Via Guido Rossa, 22/c – IT 30037 SCORZE' (VE)

nella Sede Operativa di  
*Operative Unit - Siège Opérationnel*

Via Guido Rossa, 22/c – IT 30037 SCORZE' (VE)

è conforme alla norma  
*is in compliance with the standard - est conforme à la norme*

**UNI CEI EN ISO 13485-2016 (ISO 13485-2016)**

per i seguenti Processi  
*concerning the following kinds of Processes - pour les suivants Processus*

**Progettazione e produzione di componenti per impianti di distribuzione  
dei gas medicinali e per vuoto e per impianti di evacuazione dei gas anestetici.**

*Design and manufacture of components for pipeline systems for compressed medical gases  
and vacuum and for anaesthetic gas scavenging disposal systems.*

*Conception et fabrication de composants pour systèmes de distribution de gaz médicaux comprimés  
et de vide e pour Systèmes d'évacuation de gaz d'anesthésie non réutilisables*

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la Certificazione in vigore applicabili  
*This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable*

*Ce certificat est soumis à la conformité avec les termes et conditions du règlement de certification applicable.*

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*In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language*

*En cas de divergence entre les langues utilisées pour la traduction du contenu de ce certificat, veuillez vous référer à la langue italienne*

L'AMMINISTRATORE DELEGATO

MANAGING DIRECTOR



Dr. Ing. Roberto Cusolito

Data di Prima Emissione

*Forst Issue Date*

2005-12-01

Data di Rinnovo

*Renewal Date*

2020-11-19

Data di Scadenza

*Expiration Date*

2023-06-05



SGQ N° 023A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC  
*Signatory of EA, IAF and ILAC Mutual Recognition Agreements*



Notified Body n° 0426



ITALCERT S.r.l.  
viale Sarca, 336 - IT 20126 MILANO MI  
tel. +39 0266104876 - fax +39 0266101479  
E-mail italcert@italcert.it

**CERTIFICATE N° 062-03-00-DM**

*(in compliance with Annex II of the Directive 93/42/EEC)*

**ITALCERT**

certifies that

Full Quality Assurance System  
applied for the design, manufacture and final inspection  
of "Medical Devices" - MD -

by the manufacturer

**MD S.r.l.**

Via Guido Rossa, 22/c - 30037 SCORZÈ (VE) - ITALY

in the headquarters located in

Via Guido Rossa, 22/c  
30037 SCORZÈ (VE) - ITALY

complies with the requirements stated in

**Directive 93/42/EEC - Annex II (excluding point 4)**

and authorizes the same manufacturer to mark

**CE 0426**

in compliance with the criteria defined in Annex XII of the Directive 93/42/EEC  
the MD reported in Annex 1 of this Certificate

dr. ing. Roberto Cusolito

A blue ink signature of Roberto Cusolito, written in a cursive style.

MANAGING DIRECTOR

First Issue date  
2006-05-24

Renewal date  
2019-05-24

Expire date  
2024-05-23

This certificate must be published only in integral form and accompanied by its Annex 1.  
This certificate is the English translation of the certificate n°062-03-00-DM issued by ITALCERT Srl in Italian language.  
In case of discrepancy you must refer to the original certificate issued in Italian language.



## Annex 1 to the Certificate n° 062-03-00-DM

- page 1 of 2 -

### Active medical device intended to administer and/or remove medicines, body liquids or other substances to or from the body

- Terminal units for medical gas and vacuum pipeline systems (class IIb)
 

PF-01xx-yyyy	Base blocks for terminal units for medical gas pipeline systems
PF-02xx-yyyy	Outlets for terminal units for medical gas pipeline systems
PF-06xx-yyyy	Probes for terminal units for medical gas pipeline systems
PF-36xx-yyyy	Doublers for terminal units for medical gas pipeline systems
KT-02xx-yyyy	Maintenance kits for terminal units
PF-34xx-yyyy	Pre-installed terminal units boxes
PF-66xx-yyyy	Hose assemblies
KT-01xx-yyyy	Maintenance kits for base blocks
  
- Second stage pressure regulators for medical gas pipeline systems (class IIb)
 

PF-05xx-yyyy / PF-37xx-yyyy	Line pressure regulators for medical gas pipeline systems
KT-05xx-yyyy / KT-37xx-yyyy	Maintenance kits for line pressure regulators
PF-55xx-yyyy	High flow line pressure regulators
KT-55xx-yyyy	Maintenance kits for high flow line pressure regulators
PF-44xx-yyyy	Pre-assembled cabinets for second stage pressure regulation / line pressure stabilization and regulation cabinets
  
- Terminal units for type 1 AGSS (Anaesthetic gas scavenging systems) (class IIa)
 

PF-02Ex-yyyy	Outlets for terminal units for AGSS
PF-01Ex-yyyy	Base blocks for terminal units for AGSS
PF-06Ex-yyyy	Probes for terminal units for AGSS
KT-02Ex-yyyy	Replacement kits for terminal units for AGSS
PF-76xx-yyyy	Accessories for AGSS
  
- Flow-meters for connection with terminal units of medical gas pipeline systems (class IIa)
 

PF-26xx-yyyy	Flow meters
PF-27xx-yyyy	Humidifiers for flow meters
PF-57xx-yyyy	Flow selectors
  
- Medical suction devices
 

PF-38xx-yyyy	Vacuum regulators with collection for collection jar or hose barb fitting (class IIa)
PF-50xx-yyyy	Vacuum regulator – Probe – Flexible hose kit – Hose barb fitting/collection jar – filter (class IIb)
  
- Shut-off area valves and Vacuum control units (class IIb)
 

PF-03xx-yyyy	Shut-off area valves for medical gases and vacuum
PF-35xx-yyyy	Vacuum control units
PF-45xx-yyyy	Area valves pre-assembled cabinets
PF-46xx-yyyy	Shut off valves pre-assembled cabinets for fire control
PF-48xx-yyyy	Shut off line valves pre-assembled cabinets
PF-49xx-yyyy	Medical gas distribution system management cabinet
PF-61xx-yyyy	Shut-off area valves for medical gases and vacuum
PF-64xx-yyyy	AVSU (Area Valve Service Unit)
KT-61xx-yyyy	Maintenance kits for shut-off area valves
PF-74xx-yyyy	Area shut-off valves for compressed medical gases and vacuum
KT-74xx-yyyy	Connecting kits for area shut-off valves PF-74xx-yyyy
KT-76xx-yyyy	Maintenance kits for area shut-off valves PF-74xx-yyyy

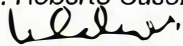
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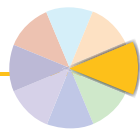
## **Annex 1 to the Certificate n° 062-03-00-DM**

- page 2 of 2 -

- High pressure systems (class IIb)
  - PF-40xF-yyyy Pigtails for cylinders
  - PF-40xP-yyyy Pigtails for cylinder bundles
  - PF-40xT-yyyy High pressure flexible connections
  - PF-42xy-zzzz Cylinder manifolds
  
- First stage regulation devices (class IIb)
  - PF-43xx-yyyy First stage regulators for medical gas cylinder manifolds
  - KT-43xx-yyyy Maintenance kits for first stage pressure regulators
  - PF-51xx-yyyy Automatic change-over decompression units for medical gases
  - PF-52xx-yyyy Automatic change-over
  - PF-53xx-yyyy Emergency decompression units for medical gases
  - PF-62xx-yyyy First stage regulators for medical gas cylinder manifolds
  - KT-62xx-yyyy Maintenance kits for first stage pressure regulators
  - PF-70xx-yyyy High-flow manual change-over safety decompression station for medical gases
  
- Double-stage regulation devices (class IIb)
  - PF-54xx-yyyy Double-stage decompression units for medical gases
  - PF-56xx-yyyy Double-stage emergency decompression units for medical gases
  - PF-59xx-yyyy HTM 02-01 automatic manifolds for medical gases
  - PF-60xx-yyyy HTM 02-01 emergency reserve manifolds for medical gases

Milan, 2019-05-24

*dr. ing. Roberto Cusolito*  
  
Managing Director






## Surface mount installation systems for terminal units





### IDENTIFICATION

- ▶ Surface mount wall outlet box for installation of medical gas and AGSS terminal units (model for systems with centralized blower)
- ▶ Equipped with wall box cover with bas-relief moulding for gas identification sticker
- ▶ Construction in white ABS with threaded inserts for fastening terminal units
- ▶ Modular design to allow multiple boxes to be installed in series

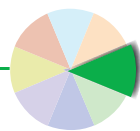
### SURFACE MOUNT BOX

CODE	DESCRIPTION	PACKAGING		
		 type	 kg	 pcs
PF-2100-4000	Surface mount box for terminal units	unboxed	0.14	1

### GAS IDENTIFICATION STICKERS

CODE	GAS	SYMBOL	COLOR	PACKAGING	
				 type	 pcs
ET-2100-000V	Vacuum	Vac	Yellow	bag	1
ET-2100-00O2	Oxygen	O <sub>2</sub>	White	bag	1
ET-2100-00AC	Medical Air	Air	Black - White	bag	1
ET-2100-0N2O	Nitrous Dioxide	N <sub>2</sub> O	Blue	bag	1
ET-2100-0CO2	Carbon Dioxide	CO <sub>2</sub>	Grey	bag	1
ET-2100-0AC8	Instruments Air	Air-800	Black - White	bag	1
ET-2100-00EV	Anaesthetic gas scavenging	AGSS	Magenta	bag	1





## Humidifiers for flow meters for oxygen therapy

### IDENTIFICATION

- ▶ Humidifier for oxygen therapy designed to contain demineralized water used to increase the relative humidity of the oxygen supplied to the patient
- ▶ Autoclavable polycarbonate jar
- ▶ Autoclavable plastic cap
- ▶ Internal silicone rubber tube complete with filter for diffusion of oxygen in the water
- ▶ Hose connector on humidifier cap for connection to patient administration devices (masks, nasal catheters...)
- ▶ Indication of water filling limit and safety information
- ▶ Latex-safe humidifier assembly

### CE MARKING

Notified body 0426

CE marking in risk class II A in accordance with Legislative Decree 24 February 1997, no. 46 "Implementation of Directive 93/42/EEC, concerning Medical Devices" and further modifications

### REFERENCE STANDARDS

**UNI 11341:** "Bubbling humidifiers for medical use - fundamental requirements"

**HTM 02-01:** "Medical gas pipeline systems"

\*Validity of the standards is referred to the current year



- ▶ Capacity: 250 cc
- ▶ Connection with flow meter via nickel-plated brass union with G 1/4" or 9/16" fitting
- ▶ Maximum pressure: 500 kPa
- ▶ Maximum flow rate: 20 l/min
- ▶ Sterilizable in autoclave at 121 °C
- ▶ Time for sterilization cycle: 20 minutes







# CERTIFICATE

## İNSPİTAL MEDİKAL TEKNOLOJİ ANONİM ŞİRKETİ

KARAOĞLAN MAHALLESİ KÜME EVLERİ NO: 745 GÖLBAŞI - ANKARA - TURKEY

DESIGN, DEVELOPMENT, PRODUCTION, INSTALLATION, DISTRIBUTION AND SERVICES OF MEDICAL GAS, MEDICAL AIR AND VACUUM SYSTEMS AND EQUIPMENTS, STAINLESS STEEL HOSPITAL EQUIPMENTS, SCRUB SINKS, ULTRASONIC CLEANING UNITS, ASPIRATION BAG SUCTION LINER AND ACCESSORIES, MEDICAL COPPER TUBINGS AND FITTINGS, ELECTROSURGICAL UNITS, SURGICAL SUCTION UNITS, OPERATING ROOM TABLES AND ACCESSORIES, OPERATING ROOM LAMPS, EXAMINATION LAMPS

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 11038
Initial Certification Date	: 02 August 2018
Certification Date	: 28 July 2021
Expiration Date	: 27 July 2024

Kiwa Belgelendirme Hizmetleri A.Ş.  
İTOSB 9. Cadde No. 15 Tepeören Tuzla  
İstanbul / Turkey

Tel: + 90 216 593 25 75  
Faks: + 90 216 593 25 74  
[info@kiwa.com.tr](mailto:info@kiwa.com.tr)  
[www.kiwa.com.tr](http://www.kiwa.com.tr)

General Manager



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





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

**Certificate Number: 1984-MDD-18-535**

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:**

**İNSPİTAL MEDİKAL TEKNOLOJİ ANONİM ŞİRKETİ**

Karaoğlu Mahallesi Karaoğlu Küme Evleri No:745 Gölbaşı/ Ankara, Turkey

**Products:** Flowmeters, Anaesthetic Gas Scavenging (AGSS) System, Area Gas Control Panels, Pipelines and Stations for Medical Gases, Pipelines and Stations for Vacuum, Patient Bed Head Unit, Pendant Unit, Anaesthetic Gas Scavenging Terminal Unit and Probe, Jacks and Outlet for Compressed Medical Gas, Jacks and Outlet for Vacuum, Pressure Regulator with Flowmeter, Manifold and Line Pressure Regulators, Pressure Regulator, Vacuum Regulator, Surgical Suction Unit, Central Vacuum System, Medical Copper Tubings, Electrosurgical Unit

The products defined at the enclosure which is the part of this certificate and contains four page. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

**Report Number:** M.5220.03  
**Date of first issue:** 02 August 2018  
**Date of last issue:** 21 April 2021  
**Revision Number:** 02  
**Expiry Date:** 27 May 2024

**Muhteşem Gökhan Yücel**  
Head of Notified Body

21 April 2021, Istanbul, Turkey

Enclosure of the EC Certificate:

Page 1/4

**Full Quality Assurance System according to  
Medical Devices Directive 93/42/EEC Annex-II Section 3  
Certificate Number: 1984-MDD-18-535, Revision Number: 02**

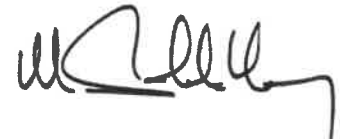
Concerned medical devices;

**Product:** Flowmeters

**Model:** FM20.11, FM20.21, FM20.31, FM20.41, FM20.51, FM20.61, FM20.71, FM20.12, FM20.22, FM20.32, FM20.42, FM20.52, FM20.62, FM20.72, FM20.13, FM20.23, FM20.33, FM20.43, FM20.53, FM20.63, FM20.73, FM20.14, FM20.24, FM20.34, FM20.44, FM20.54, FM20.64, FM20.74, FM20.15, FM20.25, FM20.35, FM20.45, FM20.55, FM20.65, FM20.75, FM20.16, FM20.26, FM20.36, FM20.46, FM20.56, FM20.66, FM20.76, FM20.17, FM20.27, FM20.37, FM20.47, FM20.57, FM20.67, FM20.77, FM20.18, FM20.28, FM20.38, FM20.48, FM20.58, FM20.68, FM20.78, FM21.11, FM21.21, FM21.31, FM21.41, FM21.51, FM21.61, FM21.71, FM21.12, FM21.22, FM21.32, FM21.42, FM21.52, FM21.62, FM21.72, FM21.13, FM21.23, FM21.33, FM21.43, FM21.53, FM21.63, FM21.73, FM21.14, FM21.24, FM21.34, FM21.44, FM21.54, FM21.64, FM21.74, FM21.15, FM21.25, FM21.35, FM21.45, FM21.55, FM21.65, FM21.75, FM21.16, FM21.26, FM21.36, FM21.46, FM21.56, FM21.66, FM21.76, FM21.17, FM21.27, FM21.37, FM21.47, FM21.57, FM21.67, FM21.77, FM21.18, FM21.28, FM21.38, FM21.48, FM21.58, FM21.68, FM21.78

**Product:** Area Gas Control Panels

**Model:** GZ71.58, GZ71.59, GZ71.60, GZ71.61, GZ71.62, GZ71.63, GZ71.64, GZ71.65, GZ71.66, GZ71.67, GZ71.68, GZ71.69, GZ71.70, GZ71.71, GZ71.72, GZ71.73, GZ71.74, GZ71.75, GZ71.76, GZ71.77, GZ71.78, GZ71.79, GZ71.80, GZ71.81, GZ71.83, GZ71.84, GZ71.85, GZ71.86, GZ71.87, GZ71.88, GZ71.89, GZ71.90, GZ71.91, GZ71.92, GZ71.93



Muhteşem Gökhan Yücel  
Head of Notified Body

21 April 2021, Istanbul, Turkey



Enclosure of the EC Certificate:

Page 2/4

Full Quality Assurance System according to

Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-18-535, Revision Number: 02

Concerned medical devices;

**Product:** Pipelines and Stations for Medical Gases

**Model:** GZ71.01, GZ71.02, GZ71.03, GZ71.04, GZ71.05, GZ71.06, GZ71.07, GZ71.08, GZ71.09, GZ71.10, GZ71.11, GZ71.12, GZ71.13, GZ71.14, GZ71.15, GZ71.16, GZ71.17, GZ71.18

**Product:** Pipelines and Stations for Vacuum

**Model:** VK40.02, VK40.03, VK40.04, VK40.05, VK40.06, VK40.07, VK40.08, VK40.09, VK40.10, VK40.11, VK40.12, VK40.13, VK40.14, VK40.15

**Product:** Anaesthetic Gas Scavenging (AGSS) System

**Model:** VK50.01, VK50.02, VK50.03, VK50.04

**Product:** Pendant Unit

**Model:** FX40.05, FX40.10, FX40.15, FX40.20, FX40.25

**Product:** Patient Bed Head Unit

**Model:** GB22.10, GB22.20, GB22.30, GB22.40, GB22.01, GB22.02, GB22.03, GB22.04

**Product:** Anaesthetic Gas Scavenging Terminal Unit and Probe

**Model:** PR80.26, PR80.27, PR80.28, PR80.29, PR80.30, PR80.31, JK91.20, JK91.21, JK91.22, JK91.23, JK91.24, JK91.25, JK91.26, JK91.27, JK91.28



Muhteşem Gökhan Yücel  
Head of Notified Body

21 April 2021, Istanbul, Turkey



# CERTIFICATE

**Enclosure of the EC Certificate:**

**Page 3/4**

**Full Quality Assurance System according to**

**Medical Devices Directive 93/42/EEC Annex-II Section 3**

**Certificate Number: 1984-MDD-18-535, Revision Number: 02**

Concerned medical devices;

**Product:** Jacks and Outlet for Compressed Medical Gas

**Model:** JK90.50, JK90.51, JK90.52, JK90.53, JK90.54, JK90.55, JK90.56, JK90.57, JK90.58, JK90.70, JK90.71, JK90.72, JK90.73, JK90.74, JK90.75, JK90.76, JK90.77, JK90.78, JK90.80, JK90.81, JK90.82, JK90.83, JK90.84, JK90.85, JK90.86, JK90.87, JK90.88, JK90.90, JK90.91, JK90.92, JK90.93, JK90.94, JK90.95, JK90.96, JK90.97, JK90.98, JK91.10, JK91.11, JK91.12, JK91.13, JK91.14, JK91.15, JK91.16, JK91.17, JK91.18, PR80.01, PR80.03, PR80.04, PR80.05, PR80.06, PR80.08, PR80.09, PR80.10, PR80.11, PR80.13, PR80.14, PR80.15, PR80.16, PR80.18, PR80.19, PR80.20, PR80.21, PR80.23, PR80.24, PR80.25, PR82.01, PR82.03, PR82.04, PR82.05, PR82.06, PR82.08, PR82.09, PR82.10, PR82.11, PR82.13, PR82.14, PR82.15, PR82.16, PR82.18, PR82.19, PR82.20, PR82.21, PR82.23, PR82.24, PR82.25

**Product:** Jacks and Outlet for Vacuum

**Model:** PR80.02, PR80.07, PR80.12, PR80.17, PR80.22, PR82.02, PR82.07, PR82.12, PR82.17, PR82.22, JK90.60, JK90.61, JK90.62, JK90.63, JK90.64, JK90.65, JK90.66, JK90.67, JK90.68

**Product:** Manifold and Line Pressure Regulators

**Model:** GZ71.20, GZ71.21, GZ71.22, GZ71.23, GZ70.10, GZ70.20, GZ70.30, GZ70.40, GZ70.50

**Product:** Pressure Regulator

**Model:** FG50.10, FG50.20, FG50.40, FG50.50, FG50.11, FG50.21, FG50.41, FG50.51, FG50.12, FG50.22, FG50.42, FG50.52, FG50.13, FG50.23, FG50.43, FG50.53, FG50.14, FG50.24, FG50.44, FG50.54, FG50.15, FG50.25, FG50.45, FG50.55, FG50.16, FG50.26, FG50.46, FG50.56

**Muhteşem Gökhan Yücel**  
Head of Notified Body

21 April 2021, Istanbul, Turkey





**Enclosure of the EC Certificate:**

**Page 4/4**

**Full Quality Assurance System according to**

**Medical Devices Directive 93/42/EEC Annex-II Section 3**

**Certificate Number: 1984-MDD-18-535, Revision Number: 02**

Concerned medical devices;

**Product:** Pressure Regulator with Flowmeter

**Model:** FM21.85, FM21.86, FM21.87, FM21.88

**Product:** Vacuum Regulators

**Model:** FG50.30, FG50.31, FG50.32, FG50.33, FG50.34, FG50.35, FG50.36, FG51.01, FG51.02, FG51.03, FG51.04, FG51.05, FG51.06, FG51.07, FG52.01, FG52.02, FG52.03, FG52.04, FG52.05, FG52.06, FG52.10, FG52.11, FG52.12, FG52.13, FG52.14, FG52.15, FG53.01, FG53.02, FG53.03, FG53.04, FG53.05, FG53.06, FG53.10, FG53.11, FG53.12, FG53.13, FG53.14, FG53.15

**Product:** Surgical Suction Unit

**Model:** SU60, SU60.10, SU60.15, SU60.22, SU60.33, SU60.05

**Product:** Central Vacuum System

**Model:** AT20.75

**Product:** Electrosurgical Unit

**Model:** NS01.60, NS02.00 Touch, NS02.50, NS04.00

**Product:** Medical Copper Tubings

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

21 April 2021, Istanbul, Turkey



**AT UYGUNLUK BEYANI**  
**EC Declaration of Conformity**

Bu ürünlerin Tıbbi Cihazlar Yönetmeliğinin (MDD 93-42 EEC) son yayımlanan gereksinimlerine göre üretilip kontrol edildiğini "İNSPİRAL" markasına ait olarak tamamen kendi sorumluluğumuz altında olduğunu beyan ederiz. /We declare that, these products which belong to "İNSPİRAL" brand are completely under our responsibility also produced and checked according to the requirements of latest revision of MDD 93-42 ECC.

**Üretici firma / Manufacturer:** İNSPİRAL MEDİKAL TEKNOLOJİ ANONİM ŞİRKETİ

**Adres /Address:** Karaoğlan mah. Kümeevler cad. No:745  
Gölbaşı / Ankara TÜRKİYE

**Tel / Phone :** +90 312 619 02 22

**Faks / Fax:** +90 312 619 02 25

**E-Mail:** info@inspital.com

**Web:** www.inspital.com

**Ürün Adı / Product Name:** Medikal Gaz Sistemleri- Bölgesel Gaz Kontrol Kutuları  
Medical Gas Systems- Area Gas Control Panels

**Ürün Markası /Product Brand:** İnspital

**Ürünün Modeli /Model of the Product:**

**GZ71.58 GAZ KONTROL KUTUSU 1 GAZ W/O ALARM-SIVA ALTI**  
GZ71.58 AREA GAS CONTROL PANELS 1 GAS W/O ALARM-UNDER PLASTER  
**GZ71.59 GAZ KONTROL KUTUSU 1 GAZ ALARMLI-SIVA ALTI**  
GZ71.59 AREA GAS CONTROL PANELS 1 GAS ALARM-UNDER PLASTER  
**GZ71.60 GAZ KONTROL KUTUSU 2 GAZ W/O ALARM-SIVA ALTI**  
GZ71.60 AREA GAS CONTROL PANELS 2 GAS W/O ALARM-UNDER PLASTER  
**GZ71.61 GAZ KONTROL KUTUSU 2 GAZ ALARMLI-SIVA ALTI**  
GZ71.61 AREA GAS CONTROL PANELS 2 GAS ALARM-UNDER PLASTER  
**GZ71.62 GAZ KONTROL KUTUSU 3 GAZ W/O ALARM-SIVA ALTI**  
GZ71.62 AREA GAS CONTROL PANELS 3 GAS W/O ALARM-UNDER PLASTER  
**GZ71.63 GAZ KONTROL KUTUSU 3 GAZ ALARMLI-SIVA ALTI**  
GZ71.63 AREA GAS CONTROL PANELS 3 GAS ALARM-UNDER PLASTER  
**GZ71.64 GAZ KONTROL KUTUSU 4 GAZ W/O ALARM-SIVA ALTI**  
GZ71.64 AREA GAS CONTROL PANELS 4 GAS W/O ALARM-UNDER PLASTER  
**GZ71.65 GAZ KONTROL KUTUSU 4 GAZ ALARMLI-SIVA ALTI**  
GZ71.65 AREA GAS CONTROL PANELS 4 GAS ALARM-UNDER PLASTER  
**GZ71.66 GAZ KONTROL KUTUSU 5 GAZ W/O ALARM-SIVA ALTI**  
GZ71.66 AREA GAS CONTROL PANELS 5 GAS W/O ALARM-UNDER PLASTER  
**GZ71.67 GAZ KONTROL KUTUSU 5 GAZ ALARMLI-SIVA ALTI**  
GZ71.67 AREA GAS CONTROL PANELS 5 GAS ALARM-UNDER PLASTER  
**GZ71.68 GAZ KONTROL KUTUSU 1 GAZ W/O ALARM SIVA ÜSTÜ**  
GZ71.68 AREA GAS CONTROL PANELS 1 GAS W/O ALARM-ON PLASTER  
**GZ71.69 GAZ KONTROL KUTUSU 1 GAZ ALARMLI SIVA ÜSTÜ**  
GZ71.69 AREA GAS CONTROL PANELS 1 GAS ALARM-ON PLASTER  
**GZ71.70 GAZ KONTROL KUTUSU 2 GAZ W/O ALARM SIVA ÜSTÜ**  
GZ71.70 AREA GAS CONTROL PANELS 2 GAS W/O ALARM-ON PLASTER  
**GZ71.71 GAZ KONTROL KUTUSU 2 GAZ ALARMLI SIVA ÜSTÜ**  
GZ71.71 AREA GAS CONTROL PANELS 2 GAS ALARM-ON PLASTER  
**GZ71.72 GAZ KONTROL KUTUSU 3 GAZ W/O ALARM SIVA ÜSTÜ**  
GZ71.72 AREA GAS CONTROL PANELS 3 GAS W/O ALARM-ON PLASTER  
**GZ71.73 GAZ KONTROL KUTUSU 3 GAZ ALARMLI SIVA ÜSTÜ**  
GZ71.73 AREA GAS CONTROL PANELS 3 GAS ALARM-ON PLASTER  
**GZ71.74 GAZ KONTROL KUTUSU 4 GAZ W/O ALARM SIVA ÜSTÜ**  
GZ71.74 AREA GAS CONTROL PANELS 4 GAS W/O ALARM-ON PLASTER  
**GZ71.75 GAZ KONTROL KUTUSU 4 GAZ ALARMLI SIVA ÜSTÜ**  
GZ71.75 AREA GAS CONTROL PANELS 4 GAS ALARM-ON PLASTER  
**GZ71.76 GAZ KONTROL KUTUSU 5 GAZ W/O ALARM SIVA ÜSTÜ**  
GZ71.76 AREA GAS CONTROL PANELS 5 GAS W/O ALARM-ON PLASTER



**GZ71.77 GAZ KONTROL KUTUSU 5 GAZ ALARMLI SIVA ÜSTÜ**

GZ71.77 AREA GAS CONTROL PANELS 5 GAS ALARM-ON PLASTER

**GZ71.83 GAZ KONTROL KUTUSU 1 GAZ ALARMLI – PASLANMAZ**

GZ71.83 AREA GAS CONTROL PANELS - STAINLESS STEEL - W 1 GAS - UNDER PLASTER

**GZ71.84 GAZ KONTROL KUTUSU 2 GAZ ALARMLI – PASLANMAZ**

GZ71.84 AREA GAS CONTROL PANELS - STAINLESS STEEL - W 2 GAS - UNDER PLASTER

**GZ71.85 GAZ KONTROL KUTUSU 3 GAZ ALARMLI – PASLANMAZ**

GZ71.85 AREA GAS CONTROL PANELS - STAINLESS STEEL - W 3 GAS - UNDER PLASTER

**GZ71.86 GAZ KONTROL KUTUSU 4 GAZ ALARMLI – PASLANMAZ**

GZ71.86 AREA GAS CONTROL PANELS - STAINLESS STEEL - W 4 GAS - UNDER PLASTER

**GZ71.87 GAZ KONTROL KUTUSU 5 GAZ ALARMLI – PASLANMAZ**

GZ71.87 AREA GAS CONTROL PANELS - STAINLESS STEEL - W 5 GAS - UNDER PLASTER

**GZ71.88 GAZ KONTROL KUTUSU 1 GAZ ALARMLI - SIVA ÜSTÜ – PASLANMAZ**

GZ71.88 AREA GAS CONTROL PANELS - STAINLESS STEEL - W 1 GAS - ON PLASTER

**GZ71.89 GAZ KONTROL KUTUSU 2 GAZ ALARMLI - SIVA ÜSTÜ – PASLANMAZ**

GZ71.89 AREA GAS CONTROL PANELS - STAINLESS STEEL - W 2 GAS - ON PLASTER

**GZ71.90 GAZ KONTROL KUTUSU 3 GAZ ALARMLI - SIVA ÜSTÜ – PASLANMAZ**

GZ71.90 AREA GAS CONTROL PANELS - STAINLESS STEEL - W 3 GAS - ON PLASTER

**GZ71.91 GAZ KONTROL KUTUSU 4 GAZ ALARMLI - SIVA ÜSTÜ – PASLANMAZ**

GZ71.91 AREA GAS CONTROL PANELS - STAINLESS STEEL - W 4 GAS - ON PLASTER

**GZ71.92 GAZ KONTROL KUTUSU 5 GAZ ALARMLI - SIVA ÜSTÜ – PASLANMAZ**

GZ71.92 AREA GAS CONTROL PANELS - STAINLESS STEEL - W 5 GAS - ON PLASTER

**Uygulanan Standartlar**

Applicable Harmonized Standards:

EN 60601-1-8:2008, TS EN 7396-1:2016, TS EN 13485:2016, TS EN ISO 14971:2013, , TS EN ISO 15223-1: 2016, TS EN 62366-1:2015, EN 1041:2008+A1:2013, TS EN 62304:2006, TS EN 60601-1:2009, TS EN 60601-1-2:2015

**Uygunluk Değerlendirme Yolu:**

Conformity Assessment Route :

MDD (93/42/EEC) EK II.3

MDD (93/42/EEC) ANNEX II.3

**Ürün Sınıfı :**

EK 9, KURAL 11'e göre Sınıf IIb

Class of Product:

Annex 9, Rule11, Class IIb

GMDN Kodu / GMDN Code:

36271

Onaylanmış Kuruluş Adı/ Name of

Notified Body:

Kiwa Belgelendirme Hizmetleri A.Ş

Onaylanmış Kuruluş Adresi:

Address of Notified Body:

(İTOSB) İstanbul Tuzla Organize Sanayi Bölgesi Tepeören Mevkii34957 Tuzla-İstanbul Türkiye

Tel / Phone:

+90 216 593 25 75

E-Mail:

[posta@kiwa.com](mailto:posta@kiwa.com)

Onaylanmış Kuruluş Numarası /:

Notified Body Number

1984

CE Sertifika Numarası/

CE Certificate Number:

1984-MDD-18-535

CE İşareti Başlangıç

Tarihi/

Initial Date of CE Marking

02.08.2018

CE İşareti Bitiş Tarihi/

CE Certificate Valid

Until:

10.05.2024

Yer & Yayın Tarihi/ Place and Date of

Issue :

İstanbul, Türkiye, 21.04.2021 /

İstanbul, Turkey, 21.04.2021

**Kalite Yönetim Temsilcisi**

Quality Management

Representative

Yeşim SEKİZELMA



# Medical Gas Plants



Stainless Steel



Electrostatic Painted

## Electrostatic Painted

Explanation	Under Plaster Version Model No	On Plaster Version Model No
With 1 gas w/o alarm	GZ71.58	GZ71.68
With 1 gas with alarm	GZ71.59	GZ71.69
With 2 gas w/o alarm	GZ71.60	GZ71.70
With 2 gas with alarm	GZ71.61	GZ71.71
With 3 gas w/o alarm	GZ71.62	GZ71.72
With 3 gas with alarm	GZ71.63	GZ71.73
With 4 gas w/o alarm	GZ71.64	GZ71.74
With 4 gas with alarm	GZ71.65	GZ71.75
With 5 gas w/o alarm	GZ71.66	GZ71.76
With 5 gas with alarm	GZ71.67	GZ71.77

## Stainless Steel

Explanation	Under Plaster Version Model No	On Plaster Version Model No
With 1 gas with alarm	GZ71.83	GZ71.88
With 2 gas with alarm	GZ71.84	GZ71.89
With 3 gas with alarm	GZ71.85	GZ71.90
With 4 gas with alarm	GZ71.86	GZ71.91
With 5 gas with alarm	GZ71.87	GZ71.92

## Area Gas Control Panels

### Description

Inspital Area Gas Control Unit is manufactured to provide isolation of individual floors of medical gases in the hospital. Area Gas Control Unit includes all features required by the EN ISO 7396-1 and HTM 02-01 standards. Isolation may be required for installation, maintenance or in the case of an emergency

### Classification

- Area Gas Control Unit is manufactured HTM 02-01, HTM 2022, EN ISO 7396-1 and BS EN 15908.

### Services

- Oxygen
- Nitrous Oxide
- Medical Air 400 kPa
- Surgical Air 700 kPa
- Medical Vacuum

### Features

- Controls 1 to 5 gases, including vacuum
- Lockable covers with emergency access lock system
- Window on the cover enables the user to monitor the analog manometers without opening the covers
- Under plaster and on plaster types are available

### Alarm Unit

- Local Area Alarm

### Pressure Switches

- Pressure switches can be fitted inside the box to enable local monitoring.

## Area Gas Control Panels With Second Stage Regulator

- Second stage pressure reducing from 10 bar to 7 bar or 4 bar
- Lockable covers with emergency access lock system
- Stainless steel valve box
- Double or single regulators option
- Under plaster and on plaster types are available

Explanation	Under Plaster Version Model No	On Plaster Version Model No
With 1 gas	GZ71.83F	GZ71.88F
With 2 gas	GZ71.84F	GZ71.89F
With 3 gas	GZ71.85F	GZ71.90F
With 4 gas	GZ71.86F	GZ71.91F
With 5 gas	GZ71.87F	GZ71.92F





This is a translation of certificate N. IT94/0008

SGS

The quality management system of

**SILMET S.p.A.**

Via Martiri della Libertà, 31 - 25030 Torbole Casaglia (BS) - Italy

has been assessed and certified as meeting the requirements of

**ISO 9001 / UNI EN ISO 9001:2015**

For the following activities

**Manufacturing and trading under own brand name of copper tube plumbing for hydro-thermo sanitary plants, distribution systems of medical gases and their mixtures, air, vacuum and anesthetic evacuation gases, for air conditioning and refrigeration applications, and other industrial use and manufacturing and rolling of copper strips and sheets for building and industrial use.**

**EA Sector: 17, 29**

This certificate is valid from 04/06/2021 until 04/06/2024 and remains valid subject to satisfactory surveillance audits.

Re certification audit due before 04/06/2024.

Issue 10. Certified since 01/09/1994.

The audit leading to this certificate commenced on 17/05/2021

Previous issue certificate validity date was until 04/06/2021

Authorized by  
Paola Santarelli



SGS ITALIA S.p.A.

Via Caldera, 21 - 20153 MILANO - Italy

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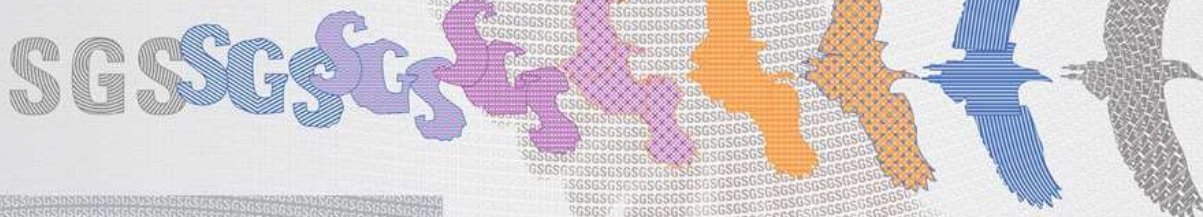
Page 1 of 1



SGQ N° 0015 A

Membro di MLA EA per gli schemi di accreditamento SGQ, SGA, PRD, PRS, ISP, GHG, LAB, LAT, PTP e RMT, di MLA IAF per gli schemi di accreditamento SGQ, SGA, SSI, FSM, PRD e PRS e di MRA ILAC per gli schemi di accreditamento LAB, MED, LAT, ISP e PTP

Signatory of EA MLA for the accreditation schemes QMS, EMS, PRD, PRS, INSP, GHG, TL, CL, PTP and RMT, of IAF MLA for the accreditation schemes QMS, EMS, ISMS, FSMS, PRD and PRS and of ILAC MRA for the accreditation schemes TL, ML, CL, INSP and PTP



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## **EC DECLARATION OF CONFORMITY**

The manufacturer:

**Silmet S.p.A. – Via Martiri della Libertà, 31  
25030 – Torbole Casaglia (BS) Italy**

Declare that the seamless, round copper tubes for water and gas in sanitary and heating applications with an outside diameter of 6 - 76,1 mm, for:

- Distributing networks for hot water and cold water
- Hot water heating systems including panel heating systems (under-floor, wall, overhead)
- Domestic gas and liquid fuel distribution
- Drainage, and disposal of other liquids and gaseous waste
- Fire suppression and extinction systems
- Pressure and vacuum systems

comply with the requirements of the following EC Directives, when installed according to national regulations

**89/106/EEC**      EU Construction Products Directive  
**97/23/EC**      EU Pressure Equipment Directive


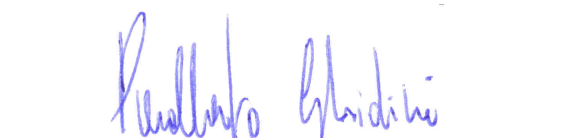
and comply with the requirements of these directives is demonstrated through conformity with the following standard:

**EN 1057:2010**      Seamless, round copper tubes for water and gas in sanitary and heating applications

Notified body: Identification No. DPC 0679

### **CSTB**

84, avenue Jean Jaurès  
Champs sur Marne  
F-77447 Marne la Vallée CEDEX 2  
Test Report No.: CA 09-010

  
\_\_\_\_\_  
Francesco Orio – Quality Manager  
\_\_\_\_\_  
Pieralberto Ghidini – Managing Director

April, 01 2010

## **BASIS FOR THE CE MARKING**

### **EN 1057:2010 Annex ZA**

Compliance with the Construction Products Directive 89/106/EEC

<b>Essential characteristic</b>	<b>Result</b>	<b>Remarks</b>
Reaction to fire	Class A1	Decision of the Commission 96/603/EC, amended 2000/605/EC
Crushing strength	NPD*	Derived from wall thickness and mechanical properties
Internal pressure	NPD*	Derived from wall thickness and mechanical properties
Dimensional tolerances	pass	All tubes must meet the specified dimensional tolerances
Resistance to high temperature	suitable for use up to 120 °C	Temperatures found in heating system pipes have non significant influence on the mechanical properties of copper. Copper tubes can also be used for higher temperatures. National regulations must be observed when used at higher temperatures
Weldability	pass	The suitability for welding is characteristic of the copper grade used for products and ensured through the control of the material composition
Tightness	pass	All tubes must be subjected to leak-tightness testing
Durability of crushing strength, internal pressure and tightness	pass	All tubes must meet the requirements regarding surface condition

\* Note: "No Performance Determined" according to EN 1057 ZA.3

### **EN 1057:2010 Annex ZB**

Compliance with the Pressure Equipment Directive 97/23/CE

<b>Essential characteristic</b>	<b>Remarks</b>
Material properties	Material properties must be met in accordance with the required mechanical properties. Copper is not susceptible to brittle fracture due to its face-centred cubic crystal structure
Conformity of material and manufacturer's certified documentation	On request, compliance of the product is confirmed by a certificate of the manufacturer according to EN 10204 Annex ZA

## **GENERAL REMARKS**

- The CE marking ensures the free movement of goods within Europe. It does not replace existing national regulations for special applications (e.g. water, gas, sanitary, heating installations, etc.)
- The copper tube is suitable for drinking water applications. The national regulations for drinking water applications remain applicable and must be followed.

This declaration is no guarantee of properties in terms of product liability. The safety information of the product documentation must be observed.

**MEDICAL**, the ideal choice for plants for the distribution of medical gases and vacuum systems.

Manufactured according to the most modern technologies on the current world market, in observance of European standard EN 13348, compatible with equipment manufactured in accordance with the Medical Device Directive 93/42/EEC, result of scientific studies and tests that guarantee the maximum compatibility for distributing the following gases and systems:

- oxygen, nitrous oxide, nitrogen, helium, carbon dioxide, xenon;
- air for breathing;
- specific mixtures of these gases mentioned above;
- air for operating surgical instruments;
- anaesthetic gases and vapours;
- vacuum.

The inner surface meets the requirements of reference standard and is also exempted from incompatible materials with medical gases. The standard EN 13348 is harmonized under the PED Directive 97/23/EC (EU Pressure Equipment Directive), therefore the Silmet MEDICAL tubes also meet the requirements of that Directive.



## TECHNICAL CHARACTERISTICS

Alloy	Cu-DHP CW024A (Cu = 99,90% min. - P = 0,015 ÷ 0,040%)		
Physical state according to EN 13348	Annealed R220	Half-Hard R250	Hard R290
Unit tensile strength – R min.	220 N/mm²	250 N/mm²	290 N/mm²
Percentage elongation – A min.	40%	20% o 30%	3%
Total carbon	C ≤ 0.02 g/m² max. in compliance with standard EN 13348		
Inner surface	Glossy		
Marking on tube	SILMET MEDICAL EN 13348 Ø X sp. Year quarter		
Dimensions and tolerances	In compliance with standard EN 13348		
Internal surface roughness	RA - 1/10 of micron		
Linear thermal expansion coefficient	0.00168 mm/m °C		
Thermal conductivity at 20°C	364 W/m · K		
* the symbol III is only present in the half-hard physical state			

## TABLE OF DIMENSIONS

external nominal diameter d	nominal thickness e						
	mm						
mm	0,7	0,8	0,9	1	1,2	1,5	2
8		R V		R V			
10		R V		R V			
12				R V			
15	R V			R V			
18				R V			
22			R V	R V		R V	
28			V	V		V	
35					V	V	
42					V	V	
54					V	V	V
R tubes in coils							
V tubes in straight lengths							



Other sizes can be supplied by agreement between the purchaser and the supplier.

For availability and feasibility of these measures and for other sizes please contact our sales department.