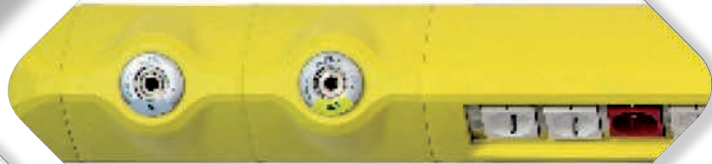


INSPI TAL



MEDICAL GAS SYSTEMS
2020



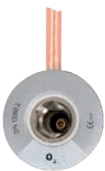
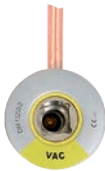
INSPIRAL Medical Gas Stations & Control Units

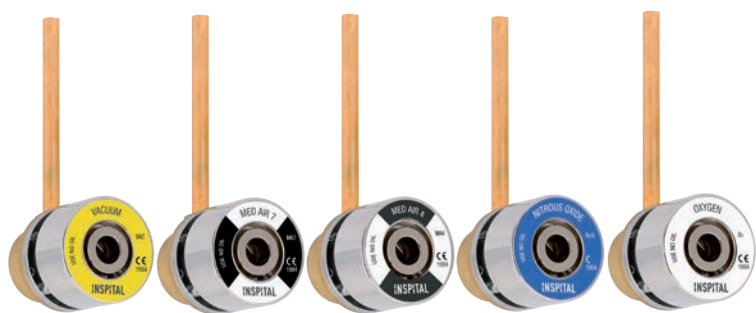
INSPIRAL offers complete solution for the medical gas system of hospitals. All the system consist of medical gas generators, manifolds, pipeline system, area control units, alarm systems, monitoring screens and the final gas outlets in Operating Theatres, ICU's and patient rooms



Medical Gas Outlets

Outlet Dia	: 45 mm
Copper Pipe Dia	: 10 mm
Production Standard	: BS 5682/EN ISO 9170-1
Color Codes	: Oxygen – White Vacuum – Yellow Nitrous Oxide – Blue Compressed Air – Black & White

						
	Oxygen	Vacuum	Air 4	Air 7	N ₂ O	CO ₂
DIN	PR80.01	PR80.02	PR80.03	PR80.04	PR80.05	PR82.01
BS	PR80.06	PR80.07	PR80.08	PR80.09	PR80.10	-



Medical Gas Outlets

Outlet Dia	: 49 mm
Copper Pipe Dia	: 10 mm
Production Standard	: BS 5682/EN ISO 9170-1
Color Codes	: Oxygen – White Vacuum – Yellow Nitrous Oxide – Blue Compressed Air – Black & White

						
	Oxygen	Vacuum	Air 4	Air 7	N ₂ O	CO ₂
DIN-90°	PR80.11	PR80.12	PR80.13	PR80.14	PR80.15	PR82.02
BS-90°	PR80.16	PR80.17	PR80.18	PR80.19	PR80.20	-
AFNOR-90°	PR80.21	PR80.22	PR80.23	PR80.24	PR80.25	-
DIN-45°	PR82.11	PR82.12	PR82.13	PR82.14	PR82.15	PR82.03
BS-45°	PR82.16	PR82.17	PR82.18	PR82.19	PR82.20	-
AFNOR-45°	PR82.21	PR82.22	PR82.23	PR82.24	PR82.25	-



Outlet Boxes, On Plaster/ Under Plaster

- Made of 304 quality S/S material
- Suitable to install on plaster / under plaster
- Several length and outlet standard alternatives

On Plaster Model	Under Plaster Model	Length	Outlet Qty
PR81.01	PR81.07	310 mm	2
PR81.02	PR81.08	460 mm	3
PR81.03	PR81.09	610 mm	4
PR81.04	PR81.10	760 mm	5
PR81.05	PR81.11	910 mm	6
PR81.06	PR81.12	1110 mm	7

- Without outlets



Plastic Outlet Boxes, Under Plaster

- Made of durable plastic material
- Suitable for under plaster installation
- Several length and outlet standard alternatives

Explanation	Length	Outlet Qty	Model No
Under Plaster	100 mm	1	PR81.17
Under Plaster	250 mm	2	PR81.18
Under Plaster	400 mm	3	PR81.19
On Plaster	100 mm	1	PR81.20

- Without outlets



Medical Gas Hoses

- Special hoses for medical gases
- Made of thermoplastic and rubber material
- Color coding according to EN 739 standard
- Suitable up to 20 bar pressure
- Inner dia: 6,7 mm Outer dia: 12 mm

Hose Type	Model No
O2, 250 cm	PR81.13
N2O, 250 cm	PR81.14
AIR, 250 cm	PR81.15
VAC, 250 cm	PR81.16

Medical Gas Outlets and Accessories



Probes

Inspital probes are produced according to international standards by using a special labelling for gases.. They are used to supply necessary gases from terminal units to the patient or medical equipments via hose connections or by direct connection to the equipment. Inspital Probes are manufactured in compliance with BS 5682:1992, DIN 13260, AFNOR NF S 90-116.

- Manufactured according to BS, DIN & AFNOR standard
- Special connections for O₂, N₂O, AIR 4 and AIR 7
- Special labeling for each gas type
- Safe hose connection
- Made of chrome plated brass material or Stainless Steel

							
		BS	DIN	AFNOR	DISS	CHEMETRON	OHMEDA
Oxygen	Stainless Steel	JK90.50	JK90.51	JK90.52	JK90.53	JK90.54	JK90.55
	Brass	JK90.56	JK90.57	JK90.58	—	—	—
Vacuum	Stainless Steel	JK90.60	JK90.61	JK90.62	JK90.63	JK90.64	JK90.65
	Brass	JK90.66	JK90.67	JK90.68	—	—	—
Air 4	Stainless Steel	JK90.70	JK90.71	JK90.72	JK90.73	JK90.74	JK90.75
	Brass	JK90.76	JK90.77	JK90.78	—	—	—
Air 7	Stainless Steel	JK90.80	JK90.81	JK90.82			
	Brass	JK90.86	JK90.87	JK90.88	—	—	—
N ₂ O	Stainless Steel	JK90.90	JK90.91	JK90.92	JK90.93	JK90.94	JK90.95
	Brass	JK90.96	JK90.97	JK90.98	—	—	—
CO ₂	Stainless Steel	JK91.10	JK91.11	JK91.12			
	Brass	JK91.16	JK91.17	JK91.18	—	—	—



Flowmeters

Insipital offers different models of flowmeters according to their gas flow scale, connection types and humidity jars that can be used with oxygen.

Flowmeters can be either connected to medical gas outlets directly or attached on rail system and connected to the outlets by flexible hoses.

Size (LxWxH)	: 80 x 48 x 145 mm
Inlet	: Whitworth GAS 1/8"
Pressure	: 4.2 Kgs/cm ² – 60 psi – 414 kPa
Flow Rate	: 0 - 15 L/min
Humidifier capacity	: 200 ml

Flowmeters L/min	Without Adaptor						
Oxygen							
Wall type	FM20.11	FM20.21	FM20.31	FM20.41	FM20.51	FM20.61	FM20.71
Rail type	FM20.12	FM20.22	FM20.32	FM20.42	FM20.52	FM20.62	FM20.72
Dual wall type	FM20.13	FM20.23	FM20.33	FM20.43	FM20.53	FM20.63	FM20.73
Dual rail type	FM20.14	FM20.24	FM20.34	FM20.44	FM20.54	FM20.64	FM20.74
Air							
Wall type	FM20.15	FM20.25	FM20.35	FM20.45	FM20.55	FM20.65	FM20.75
Rail type	FM20.16	FM20.26	FM20.36	FM20.46	FM20.56	FM20.66	FM20.76
Dual wall type	FM20.17	FM20.27	FM20.37	FM20.47	FM20.57	FM20.67	FM20.77
Dual rail type	FM20.18	FM20.28	FM20.38	FM20.48	FM20.58	FM20.68	FM20.78



Oxygen Therapy Device

Inspital Oxygen Therapy Device is appropriate to use in hospitals, emergency services and homecare units. This device is designed to adjust and control the oxygen flow.

- Chrome plated brass trunk
- High resistant polycarbonate humidifier bottle suitable for sterilization
- Maximum gas supply pressure : 200 bar
- Regulator Outlet Pressure : 3.5 - 4 bar
- Adjustable Flow : 0 - 15 L/min
- Pressure Gauge Range : 0 - 315 bar
- Sterilization Method : 121 °C

	Bull Nose	DIN	PIN INDEX
Model No	FM21.86	FM21.87	FM21.88



Oxygen Therapy Device Calibrated

- Max. gas supply pressure : 200 bar
- Regulator Outlet Pressure : 3.5 - 4 bar
- Adjustable Flow : 0 - 15 L/min
- Pressure Gauge Range : 0 - 315 bar
- Pressure reducer assy : Double stage with shutter system
- Flow setting data : 1013 mbar 23 °C
- Side gas outlet connection

	Bull Nose	DIN	PIN INDEX
Model No	FM21.69	FM21.79	FM21.89



Oxygen Therapy Device

Inspital Oxygen Therapy Device is appropriate to use in hospitals, emergency services and homecare units. This device is designed to adjust and control the oxygen flow.

- Chrome plated brass trunk
- High resistant polycarbonate humidifier bottle suitable for sterilization
- Maximum gas supply pressure : 200 bar
- Regulator Outlet Pressure : 3.5 - 4 bar
- Adjustable Flow : 0 - 15 L/min
- Inlet Pressure Gauge Range : 0 - 315 bar

	Bull Nose	DIN	PIN INDEX
Model No	FM21.96	FM21.97	FM21.98



Laboratory S/S Regulator

- Line groups with body valve
- Inlet pressure : 0 - 40 bar
- Outlet Connection : R 3/8"
- Adjustable Pressure : 0-10 bar & Argon 1,5 bar
- Stainless diaphragm

Model No	Gas type	Gas flow	Inlet Connetion
GZ70.80	Oxygen	70 m³/h	R 1/4 NPT
GZ70.81	Nitrogen	70 m³/h	R 1/4 NPT
GZ70.82	N2O	70 m³/h	R 1/4 NPT
GZ70.83	Argon 1,5 bar	15 m³/h	R 1/4 NPT
GZ70.84	CO2	12 m³/h	R 1/4 NPT
GZ70.85	Helium	40 m³/h	R 1/4 NPT
GZ70.86	Hydrogen	55 m³/h	R 1/4 NPT
GZ70.87	Dyr Air	15 m³/h	R 1/4 NPT
GZ70.88	Mixed	60 m³/h	R 1/4 NPT



Pressure Regulators

- Double stage stainless
- Inlet pressure : 0 - 230 bar
- Outlet Connection : R 3/8"
- Adjustable Pressure : 0-10 bar Argon 1,5 bar
- Stainless diaphragm,

Single Model	Double Model	Gas type	Gas flow	Inlet Connection
GZ70.60	GZ70.70	Oxygen	30 m³/h	R 3/8"
GZ70.61	GZ70.71	Nitrogen	30 m³/h	R 5/8" Inner
GZ70.62	GZ70.72	Argon	30 m³/h	R 5/8" Inner
GZ70.63	GZ70.73	CO2	11 m³/h	W21, 80X1/14
GZ70.64	GZ70.74	Helium	70 m³/h	R 5/8" Inner
GZ70.65	GZ70.75	Hydrogen	90 m³/h	W21, 80X1/14 Left
GZ70.66	GZ70.76	Dyr Air	30 m³/h	R 3/8"
GZ70.67	GZ70.77	N2O	30 m³/h	R 3/8"

Ventilator Regulators

Design to use with ventilator and direct oxygen supply at emergency, ICU and ambulances.



- Maximum gas supply pressure : 200 bar
- Regulator Outlet Pressure : 3.5 - 4 bar
- Pressure Gauge Range : 0 - 315 bar

	Bull Nose	DIN	PIN INDEX
Model No	FM21.91	FM21.92	FM21.93

Suction Accessories



Model No	Explanation
AT80.10	Suction Liner, 1 L
AT80.20	Suction Liner, 2 L
AT80.30	Suction Liner, 3 L
AT80.11	Suction Liner With Antifoam, 1 L
AT80.22	Suction Liner With Antifoam, 2 L
AT80.33	Suction Liner With Antifoam, 3 L
AT80.91	Suction Liner With Solidifying Agents, 1 L
AT80.92	Suction Liner With Solidifying Agents, 2 L
AT80.93	Suction Liner With Solidifying Agents, 3 L

Suction Liner

- No contact with patient.
- Liner and lid are made of durable plastic.
- Liners are flexible
- In bags, optionally, disinfectant, foam inhibitor and Solidifying agents are available.

The canisters are made in three sizes, to be used according to the effective requirements about the volumes expected to be suctioned, and they are manufactured in three different versions: suction liner, antifoam, solidifying agents.

Suction liner with solidifying allow us to avoid from liquid decontamination. Suction liner with antifoam finish all foam on liquid and that take advantage to use liner more efficiency.



Suction Liner Manometer Probe

- That allows to open and close to suction from top of suction liner.
- Manometer and without manometer options



Rail Attachment

Explanation	Model No
For 25 x 5 mm Rail	AT20.37



Silicone / PVC Tube

Explanation	Model No
8 x 14 mm (silicone)	AT20.47
6 x 11 mm (silicone)	AT20.46
8 x 12 mm (PVC)	AT20.44
10 x 14 mm (PVC)	AT20.45



Yankauer Tipped Hose

Explanation	Model No
1,8 Meter Hose	AT20.40
Suction Cannula tip	AT20.41



Wall Attachment

Explanation	Model No
Wall Attachment	AT20.50



Vacuum Control Connector

Explanation	Model No
Control Connector	AT20.54



Suction Cannula, Plastic

Explanation	Model No
Non-Sterile	AT20.55



Suction Liner Manometer Probe

Explanation	Model No
Manometer	AT20.78
Without Manometer	AT20.79



Tube Connector

Explanation	Model No
Non-Sterile	AT20.52



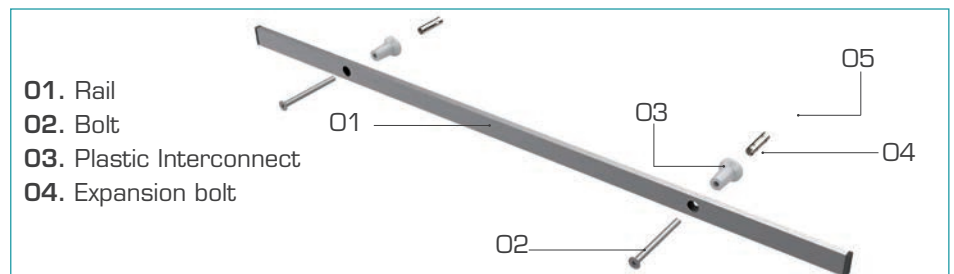
Kapkon Connector

Explanation	Model No
Kapkon Connector	AT20.53



Rail

Explanation	Model No
1 meter	AT20.56



INSPITAL

**INSPITAL Medical
Technology GmbH**

Kalkumer Str. 125

40468 Düsseldorf, GERMANY

Tel: +49 211 680 20 53-54

Fax: +49 211 680 20 55

www.inspital.com

info@inspital.com

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 for Compressed Medical Gas, Medical Gas Outlet, Vacuum Outlet, Jacks for Vacuum, Pressure Regulator with Flowmeter, Manifold and Line Pressure Regulators, Pressure Regulator, Vacuum Regulator, Surgical Suction Unit, Central Vacuum System

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

Report Number: M.5220.01
Expiry Date: 01 August 2021



02 August 2018, Istanbul, Turkey

Head of Notified Body



CERTIFICATE



Enclosure of the EC Certificate:

Page 1/17

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

Concerned medical devices;

Product: Flowmeters

Types	Model Number
Oxygen	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
Air	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
Variable Area	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
Calibrated Orifices	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

02 August 2018, Istanbul, Turkey

Head of Notified Body



Enclosure of the EC Certificate:

Page 2/17

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

Concerned medical devices;

Product: Anaesthetic Gas Scavenging (AGSS) System

Types	Model Number
Anaesthetic Gas Scavenging System 68 m ³ /h	VK50.01
Anaesthetic Gas Scavenging System 120 m ³ /h	VK50.02
Anaesthetic Gas Scavenging System 2X68 m ³ /h	VK50.03
Anaesthetic Gas Scavenging System 2X120 m ³ /h	VK50.04

Product: Area Gas Control Panels

Types	Model Number
Area Gas Control Panels 1 Gas W/O Alarm-Under Plaster	GZ71.58
Area Gas Control Panels 1 Gas Alarm-Under Plaster	GZ71.59
Area Gas Control Panels 2 Gas W/O Alarm-Under Plaster	GZ71.60
Area Gas Control Panels 2 Gas Alarm-Under Plaster	GZ71.61
Area Gas Control Panels 3 Gas W/O Alarm-Under Plaster	GZ71.62
Area Gas Control Panels 3 Gas Alarm-Under Plaster	GZ71.63
Area Gas Control Panels 4 Gas W/O Alarm-Under Plaster	GZ71.64
Area Gas Control Panels 4 Gas Alarm-Under Plaster	GZ71.65
Area Gas Control Panels 5 Gas W/O Alarm-Under Plaster	GZ71.66
Area Gas Control Panels 5 Gas Alarm-Under Plaster	GZ71.67
Area Gas Control Panels 1 Gas W/O Alarm-On Plaster	GZ71.68
Area Gas Control Panels 1 Gas Alarm-On Plaster	GZ71.69
Area Gas Control Panels 2 Gas W/O Alarm-On Plaster	GZ71.70
Area Gas Control Panels 2 Gas Alarm-On Plaster	GZ71.71
Area Gas Control Panels 3 Gas W/O Alarm-On Plaster	GZ71.72
Area Gas Control Panels 3 Gas Alarm-On Plaster	GZ71.73
Area Gas Control Panels 4 Gas W/O Alarm-On Plaster	GZ71.74



02 August 2018, Istanbul, Turkey

Head of Notified Body



Enclosure of the EC Certificate:

Page 3/17

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

Concerned medical devices;

Product: Area Gas Control Panels

Types	Model Number
Area Gas Control Panels 4 Gas Alarm-On Plaster	GZ71.75
Area Gas Control Panels 5 Gas W/O Alarm-On Plaster	GZ71.76
Area Gas Control Panels 5 Gas Alarm-On Plaster	GZ71.77
Digital Alarm Panels - Single Gas	GZ71.78
Digital Alarm Panels - Double Gas	GZ71.79
Digital Alarm Panels - Triple Gas	GZ71.80
Digital Alarm Panels - Five Gas	GZ71.81
Area Gas Control Panels - Stainless Steel - W 1 Gas - Under Plaster	GZ71.83
Area Gas Control Panels - Stainless Steel - W 2 Gas - Under Plaster	GZ71.84
Area Gas Control Panels - Stainless Steel - W 3 Gas - Under Plaster	GZ71.85
Area Gas Control Panels - Stainless Steel - W 4 Gas- Under Plaster	GZ71.86
Area Gas Control Panels - Stainless Steel - W 5 Gas - Under Plaster	GZ71.87
Area Gas Control Panels - Stainless Steel - W 1 Gas - On Plaster	GZ71.88
Area Gas Control Panels - Stainless Steel - W 2 Gas - On Plaster	GZ71.89
Area Gas Control Panels - Stainless Steel - W 3 Gas - On Plaster	GZ71.90
Area Gas Control Panels - Stainless Steel - W 4 Gas - On Plaster	GZ71.91
Area Gas Control Panels - Stainless Steel - W 5 Gas - On Plaster	GZ71.92
Central Alarm Panels	GZ71.93



02 August 2018, Istanbul, Turkey

Head of Notified Body



Enclosure of the EC Certificate:

Page 4/17

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

Concerned medical devices;

Product: Pipelines and Stations for Medical Gases

Types	Model Number
Oxygen Station 40 M3/H - Double Chain	GZ71.01
Oxygen Station 40 M3/H - Triple Chain	GZ71.02
Oxygen Station 40 M3/H - Five Chain	GZ71.03
Oxygen Station 150 M3/H - Five	GZ71.04
Oxygen Station 150 M3/H - Four	GZ71.05
Oxygen Station 150 M3/H - Five Chain - 4 Pieces	GZ71.06
Oxygen Station 150 M3/H - Five Chain - 6 Pieces	GZ71.07
Oxygen Station 150 M3/H - Five Chain - 8 Pieces	GZ71.08
Oxygen Station 40 M3/H	GZ71.09
Nitrousoxide Station 40 M3/H - Double Chain	GZ71.10
Nitrousoxide Station 40 m3/h - Triple Chain	GZ71.11
Nitrousoxide Station 40 m3/h - Five Chain	GZ71.12
Nitrousoxide Station 150 m3/h - Five Chain	GZ71.13
Nitrousoxide Station 150 m3/h - Four Chain	GZ71.14
Nitrousoxide Station 150 m3/h - Five Chain - 4 pieces	GZ71.15
Nitrousoxide Station 150 m3/h - Five Chain - 6 pieces	GZ71.16
Nitrousoxide Station 150 m3/h - Five Chain - 8 pieces	GZ71.17
Nitrousoxide Station 40 m3/h	GZ71.18



02 August 2018, Istanbul, Turkey

Head of Notified Body

Enclosure of the EC Certificate:

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

Concerned medical devices;

Product: Pipelines and Stations for Vacuum

Types	Model Number
Central Vacuum Station 47X2	VK40.02
Central Vacuum Station 47X3	VK40.03
Central Vacuum Station 100X2	VK40.04
Central Vacuum Station 100X3	VK40.05
Central Vacuum Station 200X2	VK40.06
Central Vacuum Station 200X3	VK40.07
Central Vacuum Station 47X2 Horizontal	VK40.08
Central Vacuum Station 47X3 Horizontal	VK40.09
Central Vacuum Station 100X2 Horizontal	VK40.10
Central Vacuum Station 100X3 Horizontal	VK40.11
Central Vacuum Station 200X2 Horizontal	VK40.12
Central Vacuum Station 200X3 Horizontal	VK40.13
Mini Vacuum Station (25)	VK40.14
Mini Vacuum Station (2X10)	VK40.15

Product: Pendant Unit

Types	Model Number
Pendant with Monitor Shelves	FX40.05
Single Joint Pendant with Double Shelves	FX40.10
Double Joint Pendant with Double Shelves	FX40.15
Multi movement Pendant with Shelves	FX40.20
Multi movement Pendant with Double Shelves	FX40.25



02 August 2018, Istanbul, Turkey

Head of Notified Body

Enclosure of the EC Certificate:

Page 6/17

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

Concerned medical devices;

Product: Patient Bed Head Unit

Types	Model Number
Patient Bed- Three Channels and Double Lamp-Single Bed - 3 Pcs	GB22.10
Patient Bed- Three Channels and Double Lamp-Double Bed - 6 Pcs	GB22.20
Patient Bed- Three Channels and Double Lamp-Single Bed - 4 Pcs	GB22.30
Patient Bed- Three Channels and Double Lamp-Double Bed - 8 Pcs	GB22.40
Patient Bed- Double Channels and Double Rail-Single Bed - 6 Pcs-Wall	GB22.01
Patient Bed- Double Channels and Double Rail-Double Bed - 12 Pcs-Wall	GB22.02
Patient Bed- Double Channels and Double Rail-Single Bed - 6 Pcs-Ceiling	GB22.03
Patient Bed- Double Channels and Double Rail-Double Bed - 12 Pcs-Ceiling	GB22.04

Product: Anaesthetic Gas Scavenging Terminal Unit and Probe

Types	Model Number
AGSS Teminal Units BS	PR80.26
AGSS Teminal Units BS	PR80.27
AGSS Teminal Units/ DIN (Ventury Type) on Plaster	PR80.28
AGSS Teminal Units/ DIN (Ventury Type) under Plaster	PR80.29



02 August 2018, Istanbul, Turkey

Head of Notified Body



CERTIFICATE



Enclosure of the EC Certificate:

Page 7/17

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

Concerned medical devices;

Product: Anaesthetic Gas Scavenging Terminal Unit and Probe

Types	Model Number
AGSS Teminal Units/ DIN (Ventury Type)	PR80.30
AGSS Teminal Units/ DIN	PR80.31
AGSS Prob-Stainless Steel/ BS	JK91.20
AGSS Prob- Stainless Steel/ DIN	JK91.21
AGSS Prob- Stainless Steel/ AFNOR	JK91.22
AGSS Prob- Stainless Steel/ DISS	JK91.23
AGSS Prob- Stainless Steel/ CHEMETRON	JK91.24
AGSS Prob- Stainless Steel/ OHMEDA	JK91.25
AGSS Prob- Brass/ BS	JK91.26
AGSS Prob- Brass/ DIN	JK91.27
AGSS Prob- Brass/ AFBOR	JK91.28

Product: Jacks for Compressed Medical Gas

Types	Model Number
Probes - Oxygen - Stainless Steel/ BS	JK90.50
Probes - Oxygen - Stainless Steel/ DIN	JK90.51
Probes - Oxygen - Stainless Steel/ AFNOR	JK90.52
Probes - Oxygen - Stainless Steel/ DISS	JK90.53
Probes - Oxygen - Stainless Steel/ CHEMETRON	JK90.54
Probes - Oxygen - Stainless Steel/ OHMEDA	JK90.55
Probes - Oxygen - Brass/ BS	JK90.56
Probes - Oxygen - Brass/ DIN	JK90.57

02 August 2018, Istanbul, Turkey

Head of Notified Body



Enclosure of the EC Certificate:

Page 8/17

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

Concerned medical devices;

Product: Jacks for Compressed Medical Gas

Types	Model Number
Probes - Oxygen - Brass/ AFNOR	JK90.58
Probes - Vacuum - Stainless Steel/ BS	JK90.60
Probes - Air 4 - Stainless Steel/ BS	JK90.70
Probes - Air 4 - Stainless Steel/ DIN	JK90.71
Probes - Air 4 - Stainless Steel/ AFNOR	JK90.72
Probes - Air 4 - Stainless Steel/ DISS	JK90.73
Probes - Air 4 - Stainless Steel/ CHEMETRON	JK90.74
Probes - Air 4 - Stainless Steel/ OHMEDA	JK90.75
Probes - Air 4 - Brass/ BS	JK90.76
Probes - AIR 4 - Brass/ DIN	JK90.77
Probes - AIR 4 - Brass/ AFNOR	JK90.78
Probes - Air 7 - Stainless Steel/ BS	JK90.80
Probes - Air 7 - Stainless Steel/ DIN	JK90.81
Probes- Air 7 - Stainless Steel/ AFNOR	JK90.82
Probes- Air 7 - Stainless Steel/ DISS	JK90.83
Probes- Air 7 - Stainless Steel/ CHEMETRON	JK90.84
Probes- Air 7 - Stainless Steel/ OHMEDA	JK90.85
Probes- Air 7 - Brass/ BS	JK90.86
Probes- Air 7 - Brass/ DIN	JK90.87
Probes- Air 7 - Brass / AFNOR	JK90.88
Probes- N2O - Stainless Steel / BS	JK90.90
Probes- N2O - Stainless Steel/ DIN	JK90.91
Probes- N2O - Stainless Steel/ AFNOR	JK90.92
Probes- N2O - Stainless Steel/ DISS	JK90.93



02 August 2018, Istanbul, Turkey

Head of Notified Body

Enclosure of the EC Certificate:

Page 9/17

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

Concerned medical devices;

Product: Jacks for Compressed Medical Gas

Types	Model Number
Probes- N2O - Stainless Steel/ CHEMETRON	JK90.94
Probes- N2O - Stainless Steel/ OHMEDA	JK90.95
Probes- N2O - Brass/ BS	JK90.96
Probes- N2O - Brass/ DIN-1	JK90.97
Probes- N2O - Brass/ AFNOR	JK90.98
Probes- CO2 - Stainless Steel/ BS	JK91.10
Probes- CO2 - Stainless Steel/ DIN	JK91.11
Probes- CO2 - Stainless Steel/ AFNOR	JK91.12
Probes- CO2 - Stainless Steel/ DISS	JK91.13
Probes- CO2 - Stainless Steel/ CHEMETRON	JK91.14
Probes- CO2 - Stainless Steel/ OHMEDA	JK91.15
Probes- CO2 - Brass / BS	JK91.16
Probes- CO2 - Brass/ DIN	JK91.17
Probes- CO2 - Brass/ AFNOR	JK91.18

Product: Medical Gas Outlet

Types	Model Number
Medical Gas Outlets Oxygen - 10 MM / DIN	PR80.01
Medical Gas Outlets Air 4 - 10 MM / DIN	PR80.03
Medical Gas Outlets Air 7 - 10 MM / DIN	PR80.04
Medical Gas Outlets N2O - 10 MM / DIN	PR80.05
Medical Gas Outlets Oxygen - 10 MM / BS	PR80.06



02 August 2018, Istanbul, Turkey

Head of Notified Body

Enclosure of the EC Certificate:

Page 10/17

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

Concerned medical devices;

Product: Medical Gas Outlet

Types	Model Number
Medical Gas Outlets Air 4 - 10 MM / BS	PR80.08
Medical Gas Outlets Air 7 - 10 MM / BS	PR80.09
Medical Gas Outlets N2O - 10 MM / BS	PR80.10
Medical Gas Outlets Oxygen - 8 MM / DIN	PR80.11
Medical Gas Outlets Air 4 - 8 MM / DIN	PR80.13
Medical Gas Outlets Air 7 - 8 MM / DIN	PR80.14
Medical Gas Outlets N2O - 8 MM / DIN	PR80.15
Medical Gas Outlets Oxygen - 8 MM / BS	PR80.16
Medical Gas Outlets Air 4 - 8 MM / BS	PR80.18
Medical Gas Outlets Air 7 - 8 MM / BS	PR80.19
Medical Gas Outlets N2O - 8 MM / BS	PR80.20
Medical Gas Outlets Oxygen - 8 MM / AFNOR	PR80.21
Medical Gas Outlets Air 4 - 8 MM / AFNOR	PR80.23
Medical Gas Outlets Air 7 - 8 MM / AFNOR	PR80.24
Medical Gas Outlets N2O - 8 MM / AFNOR	PR80.25
Medical Gas Outlets Oxygen - 10 MM / DIN	PR82.01
Medical Gas Outlets Air 4 - 10 MM / DIN	PR82.03
Medical Gas Outlets Air 7 - 10 MM / DIN	PR82.04
Medical Gas Outlets N2O - 10 MM / DIN	PR82.05
Medical Gas Outlets Oxygen - 10 MM / BS	PR82.06
Medical Gas Outlets Air 4 - 10 MM / BS	PR82.08
Medical Gas Outlets Air 7 - 10 MM / BS	PR82.09
Medical Gas Outlets N2O - 10 MM / BS	PR82.10
Medical Gas Outlets Oxygen - 8 MM / DIN	PR82.11



02 August 2018, Istanbul, Turkey

Head of Notified Body



Enclosure of the EC Certificate:

Page 11/17

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

Concerned medical devices;

Product: Medical Gas Outlet

Types	Model Number
Medical Gas Outlets Air 4 - 8 MM / DIN	PR82.13
Medical Gas Outlets Air 7 - 8 MM / DIN	PR82.14
Medical Gas Outlets N2O - 8 MM / DIN	PR82.15
Medical Gas Outlets Oxygen - 8 MM / BS	PR82.16
Medical Gas Outlets Air 4 - 8 MM / BS	PR82.18
Medical Gas Outlets Air 7 - 8 MM / BS	PR82.19
Medical Gas Outlets N2O - 8 MM / BS	PR82.20
Medical Gas Outlets Oxygen - 8 MM / AFNOR	PR82.21
Medical Gas Outlets Air 4 - 8 MM / AFNOR	PR82.23
Medical Gas Outlets Air 7 - 8 MM / AFNOR	PR82.24
Medical Gas Outlets N2O - 8 MM / AFNOR	PR82.25

Product: Vacuum Outlet

Types	Model Number
Medical Gas Outlets Vacuum - 10 MM / DIN	PR80.02
Medical Gas Outlets Vacuum - 10 MM / BS	PR80.07
Medical Gas Outlets Vacuum - 8 MM / DIN	PR80.12
Medical Gas Outlets Vacuum - 8 MM / BS	PR80.17
Medical Gas Outlets Vacuum - 8 MM / AFNOR	PR80.22
Medical Gas Outlets Vacuum - 10 MM / DIN	PR82.02
Medical Gas Outlets Vacuum- 10 MM / BS	PR82.07



02 August 2018, Istanbul, Turkey

Head of Notified Body

Enclosure of the EC Certificate:

Page 12/17

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

Concerned medical devices;

Product: Vacuum Outlet

Types	Model Number
Medical Gas Outlets Vacuum- 8 MM / DIN	PR82.12
Medical Gas Outlets Vacuum- 8 MM / BS	PR82.17
Medical Gas Outlets Vacuum- 8 MM / AFNOR	PR82.22

Product: Jacks for Vacuum

Types	Model Number
Probes - Vacuum - Stainless Steel/ BS	JK90.60
Probes - Vacuum - Stainless Steel/ DIN	JK90.61
Probes - Vacuum - Stainless Steel/ AFNOR	JK90.62
Probes - Vacuum - Stainless Steel/ DISS	JK90.63
Probes - Vacuum - Stainless Steel/ CHEMETRON	JK90.64
Probes - Vacuum - Stainless Steel/ OHMEDA	JK90.65
Probes - Vacuum - Brass / BS	JK90.66
Probes - Vacuum - Brass / DIN	JK90.67
Probes - Vacuum - Brass / AFNOR	JK90.68

Product: Manifold and Line Pressure Regulators

Types	Model Number
Manifold Sys. W. Double Regulator W/O Alarm 40 m ³ /h	GZ71.20
Manifold Sys. W. Double Regulator With Alarm 40 m ³ /h	GZ71.21
Manifold Sys. W. Double Regulator W/O Alarm 150 m ³ /h	GZ71.22
Manifold Sys. W. Double Regulator with Alarm 150 m ³ /h	GZ71.23



02 August 2018, Istanbul, Turkey

Head of Notified Body



CERTIFICATE



Enclosure of the EC Certificate:

Page 13/17

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

Concerned medical devices;

Product: Manifold and Line Pressure Regulators

Types	Model Number
H.P.R. Single Regulator 100 m ³ W/O Alarm	GZ70.10
H.P.R. Single Regulator 100 m ³ With Alarm	GZ70.20
H.P.R. Single Regulator 35-40 m ³ W/O Alarm	GZ70.30
H.P.R. Single Regulator 35-40 m ³ With Alarm	GZ70.40
H.P.R. Single Regulator 150 m ³	GZ70.50

Product: Pressure Regulator

Types	Model Number
Regulator (Without Adaptor)/ Oxygen	FG50.10
Regulator (Without Adaptor)/ Nitrous Oxide	FG50.20
Regulator (Without Adaptor)/ Vacuum	FG50.30
Regulator (Without Adaptor)/ Medical Air 4	FG50.40
Regulator (Without Adaptor)/ Medical Air 7	FG50.50
Regulator Oxygen/ BS	FG50.11
Regulator Nitrous Oxide/ BS	FG50.21
Regulator Vacuum/ BS	FG50.31
Regulator Medical Air 4/ BS	FG50.41
Regulator Medical Air 7/ BS	FG50.51
Regulator Oxygen/ DIN	FG50.12
Regulator Nitrous Oxide/ DIN	FG50.22
Regulator Vacuum/ DIN	FG50.32
Regulator Medical Air 4/ DIN	FG50.42
Regulator Medical Air 7/ DIN	FG50.52
Regulator Oxygen/ AFNOR	FG50.13

02 August 2018, Istanbul, Turkey

Head of Notified Body

Kiwa Certification Services Inc.
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



Enclosure of the EC Certificate:

Page 14/17

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

Concerned medical devices;

Product: Pressure Regulator

Types	Model Number
Regulator Nitrous Oxide/ AFNOR	FG50.23
Regulator Vacuum/ AFNOR	FG50.33
Regulator Medical Air 4/ AFNOR	FG50.43
Regulator Medical Air 7/ AFNOR	FG50.53
Regulator Oxygen/ DISS	FG50.14
Regulator Nitrous Oxide/ DISS	FG50.24
Regulator Vacuum/ DISS	FG50.34
Regulator Medical Air 4/ DISS	FG50.44
Regulator Medical Air 7/ DISS	FG50.54
Regulator Oxygen/ CHEMETRON	FG50.15
Regulator Nitrous Oxide/ CHEMETRON	FG50.25
Regulator Vacuum/ CHEMETRON	FG50.35
Regulator Medical Air 4/ CHEMETRON	FG50.45
Regulator Medical Air 7/ CHEMETRON	FG50.55
Regulator Oxygen/ OHMEDA	FG50.16
Regulator Nitrous Oxide/ OHMEDA	FG50.26
Regulator Vacuum/ OHMEDA	FG50.36
Regulator Medical Air 4/ OHMEDA	FG50.46
Regulator Medical Air 7/ OHMEDA	FG50.56



02 August 2018, Istanbul, Turkey

Head of Notified Body



CERTIFICATE



Enclosure of the EC Certificate:

Page 15/17

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

Concerned medical devices;

Product: Pressure Regulator with Flowmeter

Types	Model Number
Oxygen Therapy Device (Without Adaptor)	FM21.85
Oxygen Therapy Device Bull Nose	FM21.86
Oxygen Therapy Device Din	FM21.87
Oxygen Therapy Device Pin Index	FM21.88

Product: Vacuum Regulators

Types	Model Number
Regulator Vacuum (Without Adaptor)	FG50.30
Regulator Vacuum BS	FG50.31
Regulator Vacuum DIN	FG50.32
Regulator Vacuum NF	FG50.33
Regulator Vacuum DISS	FG50.34
Regulator Vacuum CHEMETRON	FG50.35
Regulator Vacuum OHMEDA	FG50.36
Vacuum Regulator (Without Adaptor)	FG51.01
Vacuum Regulator BS	FG51.02
Vacuum Regulator DIN	FG51.03
Vacuum Regulator NF	FG51.04
Vacuum Regulator DISS	FG51.05
Vacuum Regulator CHEMETRON	FG51.06
Vacuum Regulator OHMEDA	FG51.07

02 August 2018, Istanbul, Turkey

Head of Notified Body



CERTIFICATE



Enclosure of the EC Certificate:

Page 16/17

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

Concerned medical devices;

Product: Vacuum Regulators

Types	Model Number
Vacuum Regulator New (Without Adaptor)	FG52.01
Vacuum Regulator New BS	FG52.02
Vacuum Regulator New DIN	FG52.03
Vacuum Regulator New NF	FG52.04
Vacuum Regulator New DISS	FG52.05
Vacuum Regulator New OHMEDA	FG52.06
Vacuum Regulator Standard (Without Adaptor)	FG52.10
Vacuum Regulator Standard BS	FG52.11
Vacuum Regulator Standard DIN	FG52.12
Vacuum Regulator Standard NF	FG52.13
Vacuum Regulator Standard DISS	FG52.14
Vacuum Regulator Standard Ohmeda	FG52.15
Ventury System Suction Units (Without Adaptor)	FG53.01
Ventury System Suction Units BS	FG53.02
Ventury System Suction Units DIN	FG53.03
Ventury System Suction Units NF	FG53.04
Ventury System Suction Units DISS	FG53.05
Ventury System Suction Units OHMEDA	FG53.06
Ventury System Suction Units (Without Adaptor)	FG53.10
Ventury System Suction Units BS	FG53.11
Ventury System Suction Units DIN	FG53.12
Ventury System Suction Units NF	FG53.13
Ventury System Suction Units DISS	FG53.14
Ventury System Suction Units OHMEDA	FG53.15

02 August 2018, Istanbul, Turkey

Head of Notified Body



Enclosure of the EC Certificate:
Full Quality Assurance System according to
Medical Devices Directive 93/42/EEC Annex-II Section 3
Certificate Number: 1984-MDD-18-535

Page 17/17

Concerned medical devices;

Product: Surgical Suction Unit

Types	Model Number
Surgical Suction Units	SU60
Surgical Suction Units 2 X 3 L Vacuum Jar	SU60.10
Surgical Suction Units 2 X 5 L Vacuum Jar	SU60.15
Surgical Suction Units 2 X 2 Lt Vacuum Jar	SU60.22
Surgical Suction Units 2 X 3 Lt Vacuum Jar	SU60.33
Surgical Suction Units 2 X 3 L Reusable Vacuum Jar, Extractor	SU60.05

Product: Central Vacuum System

Types	Model Number
Central Vacuum System	AT20.75

Kiwa Certification Services Inc. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984



02 August 2018, Istanbul, Turkey

Head of Notified Body