

# CERTIFICATE



**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**

Karaoğlan Mahallesi Karaoğlan 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, Electrosurgical Unit, Medical Copper Tube

The products defined at the enclosure which is the part of this certificate and contains seventeen (17) pages. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

**Report Number:** M.5220.03  
**Date of first issue:** 02 August 2018  
**Date of last issue:** 23 July 2020  
**Revision Number:** 01  
**Expiry Date:** 01 August 2021

**Muhtesem Gökhan Yücel**  
Head of Notified Body

23 July 2020, Istanbul, Turkey

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

# 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, Revision Number: 01

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



Muhteşem Gökhan Yücel  
Head of Notified Body

23 July 2020, Istanbul, Turkey



# CERTIFICATE

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, Revision Number: 01

Concerned medical devices;

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

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

Muhteşem Gökhan Yücel  
Head of Notified Body

23 July 2020, Istanbul, Turkey

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

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, Revision Number: 01

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



Muhteşem Gökhan Yücel  
Head of Notified Body

23 July 2020, Istanbul, Turkey





# CERTIFICATE

Enclosure of the EC Certificate:

Page 4/17

Full Quality Assurance System according to

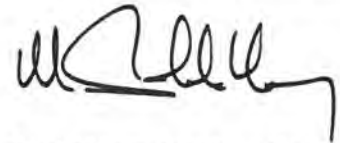
Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-18-535, Revision Number: 01

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



Muhteşem Gökhan Yücel  
Head of Notified Body

23 July 2020, Istanbul, Turkey



# CERTIFICATE

Enclosure of the EC Certificate:

Page 5/17

Full Quality Assurance System according to

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

Certificate Number: 1984-MDD-18-535, Revision Number: 01

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

Muhteşem Gökhan Yücel  
Head of Notified Body

23 July 2020, Istanbul, Turkey



## 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, Revision Number: 01

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


Muhtesem Gökhan Yücel  
Head of Notified Body

23 July 2020, Istanbul, Turkey



# 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, Revision Number:01

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

Muhteşem Gökhan Yücel  
Head of Notified Body

23 July 2020, Istanbul, Turkey



Enclosure of the EC Certificate:

Page 8/17

Full Quality Assurance System according to

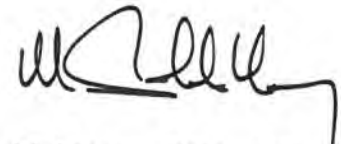
Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-18-535, Revision Number: 01

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



Muhtesem Gökhan Yücel  
Head of Notified Body

23 July 2020, Istanbul, Turkey

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

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, Revision Number: 01

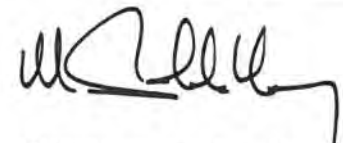
Concerned medical devices;

**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



Muhteşem Gökhan Yücel  
Head of Notified Body

23 July 2020, Istanbul, Turkey





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, Revision Number: 01

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

Muhtesem Gökhan Yücel  
Head of Notified Body

23 July 2020, Istanbul, Turkey

**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, Revision Number: 01**


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



Muhtesem Gökhan Yücel  
Head of Notified Body

23 July 2020, Istanbul, Turkey



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, Revision Number: 01

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 <sup>3</sup> /h	GZ71.20
Manifold Sys. W. Double Regulator With Alarm 40 m <sup>3</sup> /h	GZ71.21
Manifold Sys. W. Double Regulator W/O Alarm 150 m <sup>3</sup> /h	GZ71.22
Manifold Sys. W. Double Regulator with Alarm 150 m <sup>3</sup> /h	GZ71.23



Muhteşem Gökhan Yücel  
Head of Notified Body

23 July 2020, Istanbul, Turkey



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, Revision Number: 01

Concerned medical devices;

**Product:** Manifold and Line Pressure Regulators

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

Muhtesem Gökhan Yücel  
Head of Notified Body

23 July 2020, Istanbul, Turkey



Enclosure of the EC Certificate:

Page 14/17

Full Quality Assurance System according to

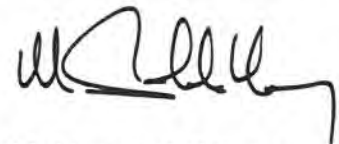
Medical Devices Directive 93/42/EEC Annex-II Section 3

Certificate Number: 1984-MDD-18-535, Revision Number: 01

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



Muhteşem Gökhan Yücel  
Head of Notified Body

23 July 2020, Istanbul, Turkey

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, Revision Number: 01

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



Muhteşem Gökhan Yücel  
Head of Notified Body

23 July 2020, Istanbul, Turkey



**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, Revision Number: 01**

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



Muhteşem Gökhan Yücel  
Head of Notified Body

23 July 2020, Istanbul, Turkey

# CERTIFICATE

Enclosure of the EC Certificate:

Page 17/17

Full Quality Assurance System according to

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

Certificate Number: 1984-MDD-18-535, Revision Number: 01

Concerned medical devices;

**Product:** Surgical Suction Unit

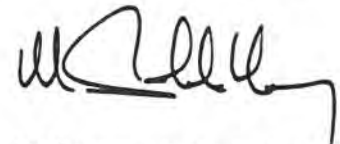
Types	Model Number
Surgical Suction Units	SU60
Surgical Suction Units 2 X 3 L Vacuum Jar	SU60.10
Surgical Suction Units 2 X 5 L Vacuum Jar	SU60.15
Surgical Suction Units 2 X 2 Lt Vacuum Jar	SU60.22
Surgical Suction Units 2 X 3 Lt Vacuum Jar	SU60.33
Surgical Suction Units 2 X 3 L Reusable Vacuum Jar,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

Product	Model Number
Central Vacuum System	AT20.75

Product	Model Number
Electrosurgical Units	NS01.60
	NS02.00 TOUCH
	NS02.50
	NS04.00

**Product:** Medical Copper Tube

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



Muhtesem Gökhan Yücel  
Head of Notified Body

23 July 2020, Istanbul, Turkey