

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:

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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

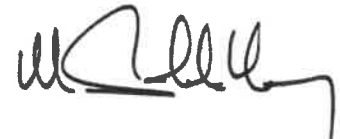
Concerned medical devices;

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



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**Full Quality Assurance System according to
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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



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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
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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



TRB
INTERNATIONAL

CERTIFICATE

İNSPİTAL MEDİKAL TEKNOLOJİ A.Ş.

KARAOĞLAN MAHALLESİ KARAOĞLAN KÜME EVLERİ NO:745 GÖLBAŞI ANKARA

ISO 9001:2015

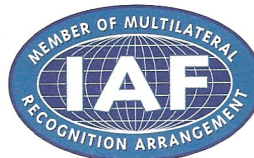
DESIGN, DEVELOPMENT, PRODUCTION, INSTALLATION AND SERVICES OF OPERATION THEATER EQUIPMENTS, INTENSIVE CARE UNIT AND EMERGENCY, MEDICAL SERVICE EQUIPMENTS, PATIENT ROOM AND CLINICAL EQUIPMENTS, STERILIZATION AND STAINLESS STEEL EQUIPMENTS, MEDICAL GAS SYSTEM AND EQUIPMENTS, SUCTION ACCESSORIES, HOSPITAL, AMBULANCE AND LABORATORY EQUIPMENT CONCEPTIONS

This certificate is valid for 3 years on condition that surveillance audits are carried out before the period of each year in accordance with the accreditation rules. With this certificate, the holder of the certificate has been audited on the address mentioned above by TRB Certification Body in accordance with the condition and requirements of the license contract and it has been registered that the company satisfies the conditions of the standard. This certificate is valid as long as the certificate holder follows TRB certification rules and the certificate is seen as valid on www.trb.com.de web site certificate inquiry section.

Certification Number : DE-QC-951
Date of Issue : 19.10.2018
Expiry Date : 18.10.2022
Certification Period : 3 Years (1. Year)
Printing Number : 03




General Manager



Deutsche
Akkreditierungsstelle
D-ZM-19486-01-00



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

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General Manager



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