



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

Karaođlan Mahallesi Karaođlan 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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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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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



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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