

CERTIFICATE

EC Certificate

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

Certificate Number: 1984-MDD-17-450

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:

**MEGASAN MEDİKAL GAZ SİSTEMLERİ TIBBİ ALET VE CİHAZLAR İNŞAAT
TAAHHÜT MADENCİLİK NAKLİYE TURİZM İTHALAT İHRACAT
SANAYİ VE TİCARET ANONİM ŞİRKETİ**

Head Office: Cumhuriyet Mah. Döğenciler Sok. Zafer İş Hanı Apt. No:33/411
Merkez, Çankırı, Turkey

Factory / Branch: Dere Mah. Aşağı Ağıl Özü Mevkii Cad. No: 18 PK:18700
Eldivan, Çankırı, Turkey

Products: Medical Gas Plants, Medical Vacuum Plant, AGSS Plant, Intensive Care Units, Zone Control and Alarm Units, Operating Theater Pendants, Flowmeters, Patient Bedhead Units, Vacuum Regulators, Low Pressure Regulators, Medical Gas Outlets, AGSS Outlets, Medical Vacuum Outlets, Gas Probes, Vacuum Probes, AGSS Probes, High Pressure Reducer

Trademarks: MEGASAN, MEGATEK, HOSPİTECH, HASTEK

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

Report Number: M.4034.09

Date of first issue: 18 July 2017

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Revision Number: 03

Expiry Date: 27 May 2024

Muhtesem Gökhan Yücel
Head of Notified Body

06 May 2020, Istanbul, Turkey



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Enclosure of the EC Certificate

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

Certificate Number: 1984-MDD-17-450, Revision Number: 03

Concerned medical devices;

Product: Medical Gas Plants

Class: IIb

Models: MG-OSxy, MG-ASxy, MG-SASxy, MG-ARSxy, MG-KGSxy, MG-KSxy, MG-HDSxy, MG-HSxy, MG-HESxy, MG-EOSxy, MG-ATSxy, MG-HSxx, MG-HSExx

Product: Vacuum Plant **Models:** MG-VSxx, MG-VSExx

Class: IIa

Product: AGSS Central **Models:** MG-AGSSx

Class: IIa

Product: Intensive Care Units

Class: IIb

Models: MG-YOYA-x, MG-YOYP-x, MG-YOYA-Ax, MG-YOYP-Ax, MG-YOD-S, MG-YOD-P, MG-YOD-A, MG-YOD-T, MG-YOD-D, MG-YOT-D, MG-YOT-S, MG-YOT-A, MG-SMK, MG-YBP-K, MG-YBP-C, MG-YBP-P, MG-YBP-T

Product: Zone Control and Alarm Units

Class: IIb

Models: MG-KKx-y, MG-KKAx-y, MG-BKx-y, MG-BKAx-y, MG-GALx, MG-GALSx, MGS-BKAx-BP-y, MGS-KKAx-BP-y

Product: Operating Theater Pendants

Class: IIb

Models: MG-PENx-V-y, MG-PENx-S-y, MG-PENx-D-y, MG-PENx-M-y, MG-PENx-MD-y, MG-PENA-MT, MG-PEN-MT

Product: Flowmeters

Class: IIb

Models: MG-F-x, MG-FLOR-Rx, MG-FLOR-x, MG-FLSR-PRx, MG-FLSS-PRx, MG-FLD-Rx, MG-FLD-x, MG-NS, MG-NEM-x, MG-FLOT-x, MG-FLOT-Rx

Product: Patient Bedhead Units

Class: IIb

Models: MG-GMYx, MG-GMYEx, MG-GMx, MG-GMx-G, MG-GMx-VN, MG-GMx-VNG, MG-GMx-VNE, MG-GMx-VNGE, MG-HBx, MG-HBxy, MG-HBV-T, MG-HBAx, MGS-HBM

Product: Vacuum Regulators

Class: IIa

Models: MG-VRMA-x, MG-VRMA-Rx, MG-VRMSV-x, MG-VRMSV-Rx, MG-VRMT-x, MG-VRMT-Rx, MG-VRMST-x, MG-VRMST-Rx, MG-GAMV-y, MG-VKTx

Muhteşemm Gökhan Yücel
Head of Notified Body

06 May 2020, Istanbul, Turkey

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Product: Low Pressure Regulators **Class: IIb**
Models: MG-xRM-y, MG-xRM-Ry, MG-IBD-x, MG-GAMx-y

Product: Gas Outlets **Class: IIb**
Models: MG-xP-yz, MG-xPK-yz, MGS-xP-yz, MGS-xPK-yz

Product: AGSS Outlets **Class: IIa**
Models: MG-AGTx, MGS-AGTx

Product: Vacuum Outlets **Class: IIa**
Models: MG-VP-yz, MG-VPK-yz, MGS-VP-yz, MGS-VPK-yz

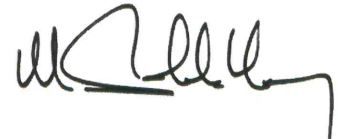
Product: Gaz Probs **Class: IIb**
Models: MG-PRxB-y, MGS-PRxB-y

Product: Vacuum Probs **Class: IIa**
Models: MG-PRVB-y, MGS-PRVB-y

Product: AGSS Probs **Class:IIa**
Models: MG-PRAGS-y, MGS-PRAGS-y

Product: High Pressure Reducer
Models: MG-YBDNx, MG-YBDTx, MG-LOCP, MG-JOCP, MG-KOLxy, MG-TIJx, MG-xDAB, MG-YBRx, MG-xR2M, MG-xR2MP, MG-TC, MG-FLOT-T, MG-ASET, MGS-MMGSNx, MGS-MMGSTx

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

06 May 2020, Istanbul, Turkey