

EC Certificate

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

Certificate Number: 1984-MDD-18-554

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:

TMS TIBBİ CİHAZ İMALAT İTHALAT VE İHRACAT SANAYİ TİCARET LİMİTED ŞİRKETİ

Temelli ASO 2. ve 3. Organize Sanayi Bölgesi Alcı (OSB) Mahallesi
2037. Cadde No:16/B Sincan Temelli Ankara,Turkey

Product	Model Number
Anesthesia device	Maxi 2300, Maxi 2200, Maxi 2100, Tms Future FX, TMS Point Mr Compatible
CO2 absorber / Canister system	TM-K 50, TM-K 50S
Flow-metering device	FM1000, FM2200, FM2300, FM2500LF, FM5000
Pressure regulator for use with medical gases	DT100, DT200, DT300
Anaesthetic gas scavenging system	AGS-500
Multi Parameter Patient Monitor	TMS FX1, TMS FX2
Oxygen / Air Blender	FM 1000 Mix

The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number: M.3075.11

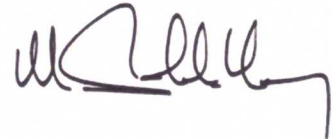
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Kiwa Belgelendirme Hizmetleri A.Ş. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984



Muhteşem Gökhan Yücel
Head of Notified Body

26 November 2020, Istanbul, Turkey