CERTIFICATE

EC Certificate

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

Certificate Number: 1984-MDD-11-102

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:

AYGÜN CERRAHİ ALETLER SANAYİ VE TİCARET ANONİM ŞİRKETİ

Kerimbey OSB Mahallesi Yaşardoğu Cad. No:76/1 Tekkeköy, Samsun, Turkey

Product: Electrical and battery operated surgical motor system
Model Name: Praxis 2, Praxis 3, BES Dermatome, Karınca 206, Karınca 208, Tesuart Ortho, Tesuart Ortho B, Praxis-3B

Product: High speed surgical motor system
Model Name: HSM, HSM-2, HSM-2 Mini Bone, HSM Micro, Acendis Neuros, Tesuart Neuros

Product: Electrical and pneumatical surgical motor systems
Model Name: Electrical Control Unit (M6-034), Pneumatic Surgical Motor

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

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Kiwa Certification Services Inc. is Notified Body under Council Directive 93/42/EEC concerning medical devices with identification number: 1984

28 May 2019, Istanbul, Turkey

Head of Notified Body

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