CERTIFICATE

EC Certificate

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

Certificate Number: 1984-MDD-18-539

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:

BIÇAKCILAR TIBBİ CİHAZLAR SANAYİ VE TİCARET ANONİM ŞİRKETİ

Osmangazi Mahallesi Gazi Caddesi No:21 Esenyurt 34522 İstanbul, Turkey

Products: Aortic Root Cannula, Coronary Artery Perfusion Cannula, B-FIX Midurethral Sling Set

The products defined at the enclosure which is the part of this certificate and contains one (1) page. The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details. Design Examination according to Medical Devices Directive 93/42/EEC Annex-II Section 4 certificate is also mandatory for class III devices covered by this certificate.

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Muhteşem Gökhan Yücel
Head of Notified Body

25 May 2021, Istanbul, Turkey

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