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

Product: Aortic Root Cannula **Class:** III
Types: 12G W/O Vent, 14G W/O Vent, 16G W/O Vent, 18G W/O Vent, 12G W/ Vent, 14G W/ Vent, 16G W/ Vent, 12G W/O Vent 35 cm, 14G W/O Vent 35 cm

Product: Coronary Artery Perfusion Cannula **Class:** III
Types: 10CH 45 degree, 12CH 45 degree, 14CH 45 degree, 10CH 90 degree, 12CH 90 degree, 14CH 90 degree

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.

Report Number: M.5045.02
Expiry Date: 28 August 2021

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

29 August 2018, Istanbul, Turkey

Head of Notified Body

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