



CERTIFICATE

EC Certificate

Production Quality Assurance System according to Medical Devices Directive 93/42/EEC Annex-V

Certificate Number: 1984-MDD-20-683

We hereby declare that an examination has been carried out following the requirements of the national legislation to which the undersigned is subject, transposing Annex-V of the Directive 93/42/EEC on medical devices. We certify that the production quality system conforms with the relevant provisions of the aforementioned legislation.

Organization:

OPTİMAL SAĞLIK ÜRÜNLERİ SANAYİ ve DIŞ TİCARET LİMİTED ŞİRKETİ

Firuzköy Mah. Poyraz Caddesi Mesken Apt. no:100/A Avcılar, İstanbul, Turkey

Products: Sterile Surgical Procedure Packs, Sterile Surgical Packs, Sterile Surgical Gowns, Sterile Surgical Drapes, Disposable Sterile Ophthalmic Surgical Instruments And Sets

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

Report Number: M.3767.09

Expiry Date: 27 May 2024

For class Is products covered by this certificate, Kiwa Belgelendirme Hizmetleri A.Ş. has audited the quality system restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions in accordance with MDD Annex V and found that the quality system meets the applicable requirements in MDD Annex V.

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

13 July 2020, İstanbul, Turkey