

CERTIFICATE



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

Certificate Number: 1984-MDD-19-577

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:

3TEKS TEKSTİL GIDA İTHALAT İHRACAT
SANAYİ VE TİCARET LİMİTED ŞİRKETİ

Head Office: Kolejtepe Mah. İnönü Cad. No:22 Şahinbey, Gaziantep, Turkey
Factory: Başpınar (Organize) OSB Mahallesi 2. Organize Sanayi Bölgesi Vali Muammer Güler Bulvarı No:5/0 Şehitkamil, Gaziantep, Turkey

Product: Sterile Disposable Surgical Drapes, Gowns and Sets

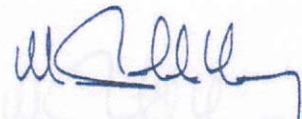
The certificate is valid till expiration date, subject to successful completion of periodical surveillance audits. Please contact Kiwa for details.

Report Number: M.5392.01
Expiry Date: 26 February 2024

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

27 February 2019 Istanbul, Turkey


Head of Notified Body

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