



CERTIFICATE



EC Certificate

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

Certificate Number: 1984-MDD-17-459

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:

BIOTEX MEDİKAL TEKSTİL İTHALAT İHRACAT SANAYİ VE TİCARET ANONİM ŞİRKETİ

HQ: İslampaşa mahallesi 2 Nolu Şehitler Caddesi No: 41/G Merkez, Rize, Turkey
Branch: Aksu OSB. Mah. 3 Nolu Cad. No: 14 Kalkandere, Rize, Turkey

Products: 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.5022.05
Date of first issue: 28 August 2017
Date of last issue: 21 May 2021
Revision Number: 02
Expiry Date: 27 May 2024

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

Muhtesem Gökhan Yücel
Head of Notified Body

21 May 2021, Istanbul, Turkey