CERTIFICATE

kiwa

BAYTEKS TEKNİK TEKSTİL SANAYİ VE TİCARET A.Ş.

ORGANİZE SANAYİ BÖLGESİ 19 NOLU CAD. NO: 9 MERKEZ - KİLİS - TURKEY

with a scope of

DISPOSABLE STERILE AND NONSTERILE SURGICAL GOWNS, DRAPES AND SETS PRODUCTION

Medical devices - Quality management systems - Requirements for regulatory purposes

"Following elements of the standard are excluded"
"7.5.3" "7.5.4" "7.5.9.2"

EN ISO 13485:2016

Certificate No	: M 10892
Initial Certification Date	: 12 January 2018
Certification Date	: 28 February 2019
Expiration Date	: 11 January 2021

General Manager

TÜRKAK
Medical Device Q.M.S.
TS EN ISO/IEC 17021-1
AB-0006-YS

MEGAFARM TRADE

Kiwa Certification Services Inc.
ITOSB 9. Cadde No. 15 Tepeören Tuzla - Istanbul - Turkey
Tel: + 90 216 593 25 75 Faks : + 90 216 593 25 74
Web: www.kiwa.com.tr E-mail: info@kiwa.com.tr

Certificate is valid till expiration date, subject to successful completion of periodical surveillance audits.
Please contact above numbers for detailed information.

Last Modified: 28 February 2019 - R 01

CERTIFICATE

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EC Certificate

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

Certificate Number: 1984-MDD-18-479

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:

BAYTEKS TEKNİK TEKSTİL SANAYİ VE TİCARET ANONİM ŞİRKETİ

Organize Sanayi Bölgesi 19 nolu Cad. No:9 Merkez /Kilis-Turkey

Products: Sterile Disposable Surgical Gown, Sterile Disposable Surgical Drapes, Sterile Disposable Surgical Packs

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

Report Number:	M.5035.02
Date of first issue:	12 January 2018
Date of last issue:	01 March 2019
Revision Number:	02
Expiry Date:	11 January 2021

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

01 March 2019, Istanbul, Turkey

Head of Notified Body

SOCIETATEA CU RASPUNDERE LIMITATA S.R.L. "MEGAFARM TRADE" REPUBLICA MOLDOVA

Kiwa Certification Services Inc.
TOSB 9. Cad. No: 15 Esenyurt, Tuzla, Istanbul, Turkey
Tel: +90 216 593 25 70 Fax: +90 216 593 25 74
Web: www.kiwa.com.tr e-mail: posta@kiwa.com.tr