



CERTIFICATE

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.5035.03
Date of first issue: 12 January 2018
Date of last issue: 16 September 2020
Revision Number: 03
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

Muhteşem Gökhan Yücel
Head of Notified Body

16 September 2020, Istanbul, Turkey



CERTIFICATE



BAYTEKS TEKNİK TEKSTİL SANAYİ VE TİCARET A.Ş.

ORGANİZE SANAYİ BÖLGESİ 19 NOLU CAD. NO: 11 MERKEZ - KİLİS - TÜRKİYE

TEK KULLANIMLIK STERİL VE NON-STERİL CERRAHİ ÖNLÜKLERİ, ÖRTÜLERİ VE SET
ÜRETİMİ, DEPOLAMASI, DAĞITIMI VE SATIŞI

kapsamında

EN ISO 13485:2016

Uluslararası Tıbbi Cihazlar Kalite Yönetim Sistemi Standardına uygun bir yönetim
sistemi kurmuştur.

"Standardın aşağıda verilen maddeleri hariç tutulmuştur"

"7.5.3" "7.5.4" "7.5.9.2"

Sertifika No : M 10892
İlk Belgelendirme Tarihi : 12 Ocak 2018
Sertifika Tarihi : 01 Şubat 2021
Son Geçerlilik Tarihi : 31 Ocak 2024

Kiwa Belgelendirme Hizmetleri A.Ş.
İTOSB 9. Cadde No: 15 Tepeören Tuzla
İstanbul / Türkiye

Tel: + 90 216 593 25 75
Faks: + 90 216 593 25 74
info@kiwa.com.tr
www.kiwa.com.tr

Sertifikalar periyodik ara denetimlerin
başarılı ile tamamlanması kaydıyla
geçerlidir. Detaylı bilgi için yukarıdaki
numaralara başvurulabilir.

Genel Müdür



Sertifika Son Güncelleme Tarihi : 01 Şubat 2021 - R 02



CERTIFICATE



BAYTEKS TEKNİK TEKSTİL SANAYİ VE TİCARET A.Ş.

ORGANİZE SANAYİ BÖLGESİ 19 NOLU CAD. NO: 11 MERKEZ - KİLİS - TURKEY

**PRODUCTION, STORAGE, DISTRIBUTION AND SALES OF DISPOSABLE STERILE
AND NON STERILE SURGICAL GOWNS, DRAPES AND SETS**

with a scope of

EN ISO 13485:2016

Has established a management system in accordance
with international Medical Devices Quality Management System Standard

"Following elements of the standard are excluded"

"7.5.3" "7.5.4" "7.5.9.2"

Certificate No	: M 10892
Initial Certification Date	: 12 January 2018
Certification Date	: 01 February 2021
Expiration Date	: 31 January 2024

Kiwa Belgelendirme Hizmetleri A.Ş.
ITOSB 9. Cadde No. 15 Tepeören Tuzla
Istanbul / Turkey

Tel: + 90 216 593 25 75
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info@kiwa.com.tr
www.kiwa.com.tr

General Manager



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

Certificate

Standard **ISO 9001:2015**

Certificate Registr. No. **01 100 1317789**

Certificate Holder:



BAYTEKS

BAYTEKS TEKNİK TEKSTİL SAN. VE TİC. A.Ş.
ORGANİZE SANAYİ BÖLGESİ 19 NO'LU CAD. NO:9
79000 MERKEZ – KİLİS / TURKEY

Scope: Design, production, processing and sales of non-woven surface fabric

Proof has been furnished by means of an audit that the requirements of ISO 9001:2015 are met.

Validity: The certificate is valid from 2020-03-18 until 2023-03-17.
First certification 2014

2020-01-23

TÜV Rheinland Cert GmbH
Am Grauen Stein · 51105 Köln