



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



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## 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  
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[www.kiwa.com.tr](http://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



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## 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  
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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