



OPTİMAL SAĞLIK ÜRÜNLERİ SANAYİ VE DIŞ TİCARET LİMİTED ŞİRKETİ

FİRUKÖY MAHALLESİ POYRAZ CADDESİ MESKEN APT. NO: 100/A AVCILAR - İSTANBUL - TURKEY

DESIGN, MANUFACTURE, DISTRIBUTION OF STERILE AND NON STERILE SURGICAL
DRAPES AND GOWNS, STERILE SURGICAL SETS, STERILE CUSTOM PROCEDURE SETS,
SINGLE USE AND REUSABLE OPHTALMIC SURGICAL DEVICES 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 8995
Initial Certification Date	: 20 March 2012
Certification Date	: 18 May 2021
Expiration Date	: 17 May 2024

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

Tel: + 90 216 593 25 75
Faks: + 90 216 593 25 74
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.



TÜRKAK BDS NO
YS-A7A9-9B61



CERTIFICATE

EC Certificate

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

Certificate Number: 1984-MDD-20-683

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:

**OPTİMAL SAĞLIK ÜRÜNLERİ
SANAYİ ve DIŞ TİCARET LİMİTED ŞİRKETİ**

Firuzköy Mah. Poyraz Caddesi Mesken Apt. no:100/A Avcılar, Istanbul, Turkey

Products: Sterile Surgical Procedure Packs, Sterile Surgical Packs, Sterile Surgical Gowns, Sterile Surgical Drapes, Disposable Sterile Ophthalmic Surgical Instruments 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.3767.09

Expiry Date: 27 May 2024

For class Is products covered by this certificate, 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

13 July 2020, Istanbul, Turkey

AT Uygunluk Beyanı EC Declaration Of Conformity



OPF019_Rev01_20.09.2019

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Üretici Firma Manufacturer	OPTIMAL SAGLIK URUNLERI SAN. VE DIS TIC. LTD. STI.
Üretici adresi Manufacturer Address	Firuzkoy Mah. Poyraz Cad. No:100/A Avcılar İstanbul / TURKEY
Üretici İletişim Bilgileri Manufacturer Communication Information	+90 212 423 10 24 Pbx +90 212 423 10 25 Fax

Onaylanmış Kuruluş Notified Body	Kiwa Belgelendirme Hizmetleri A.Ş
Onaylanmış Kuruluş Adres Notified Body address	İTOSB 9. Cadde No:15 Tepeören Tuzla İstanbul / TURKEY
Onaylanmış Kuruluş Numarası Notified Body id no	CE 1984
CE Sertifika no EC Certificate no	1984-MDD-20-683
CE Sertifika/ EC Certificate Son Geçerlilik Tarihi / Expiry Date	27 Mayıs 2024 / 27 May 2024

Biz, Tıbbi Cihazlar Direktifi 93/42/EEC (2007/47/EC) Ek V maddelerine uygun olarak aşağıda belirtilen ürünler için bütün sorumluluğu üstlenir ve ürünün aşağıda belirtilen standartlara ve diğer düzenleyici mevzuatlara uyduğumuzu beyan ederiz.

We, declare under our sole responsibility that the products below to which this declaration relates are in conformity with the following standard(s) and other regulatory laws following the provisions of Medical Device Directive 93/42 EEC (2007/47/EC) Annex V.

Ürün Bilgileri Product Information	Steril Cerrahi Setler, Cerrahi Önlükler, Cerrahi Örtüler Sterile Surgical Packs, Surgical Gowns, Surgical Drapes
Ürün Kuralı ve Sınıfı Device Rule and Class	Kural 1, Sınıf IS Rule 1, Class IS
GMDN Kodu GMDN Code	35778 Önlük, cerrahi, tek kullanımlık / Apron, surgical, single use 47783 Genel amaçlı cerrahi örtü, tek kullanımlık steril / General-purpose surgical drape, single-use, sterile 33961 Genel amaçlı cerrahi prosedür kiti, ilaçsız, tek kullanımlık / General surgical procedure kit, non-medicated, single-use

Uygulanabilir Standartlar/ Applicable Standards:

MDD 93/42/EEC, EN ISO 13485:2016/AC:2018, EN ISO 14971:2012, ISO 14644-1, TS EN 13795-1, ISO 11135
MEDDEV 2.12/1 rev.8, EN ISO 11737-2:2009

Yayın Yeri ve Tarihi/ Date and Place of Issue: İstanbul, 13.07.2020

ONAY / APPROVAL

Genel Müdür/ General Manager


OPTIMAL
SAGLIK URUNLERI SAN. VE DIS TIC. LTD. STI.
FIRUZKÖY MAH. POYRAZ CAD. NO:100/A
AVCILAR İSTANBUL / TÜRKİYE
Tic. Sic. No: 274500 / Şirket Sic. No: 274500

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<u>Ref No</u>	<u>Description</u>
OSD2004003	Ophthalmic Drape with Single LCP, 100x120 cm
OSD2004060	Ophthalmic Drape with Single LCP, 102x122 cm

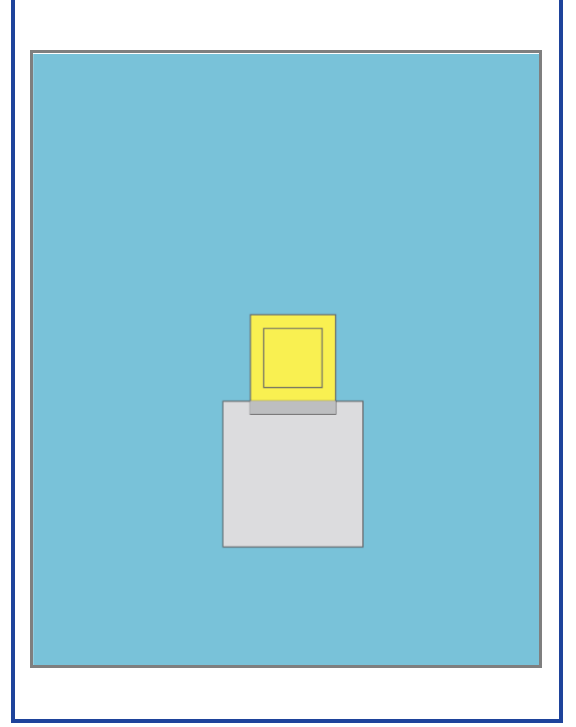


Eye Drape with Single LCP

Ref No: OSD2004003

Drape Specification:

- Fluid Repellent SMS material with high breathability, excellent conformability and resistance to tear
- 100x120 cm size
- Oval fenestrated area 10x12 cm for single eye covered with adhesive incision film 15x17 cm
- Pre attached single fluid collection pouch (21x25 cm) from high quality transparent PE material, covered flex wire on the top open edge
- Special folding for aseptic application, easy for one person to drape



Our Eye Drapes

- ✓ used to isolate areas of the patient during ophthalmology procedures
- ✓ provides convenient, efficient cost effective draping for a variety of ophthalmology procedures.
- ✓ can be provided with customized sizes to meet different draping needs.
- ✓ designed for single use and they are sterilized by ETO.
- ✓ manufactured in a ISO and CE certified facility.

OPTIMAL SAGLIK URUNLERI SANAYI VE DIS TICARET LTD. STI.

Head Office & Factory

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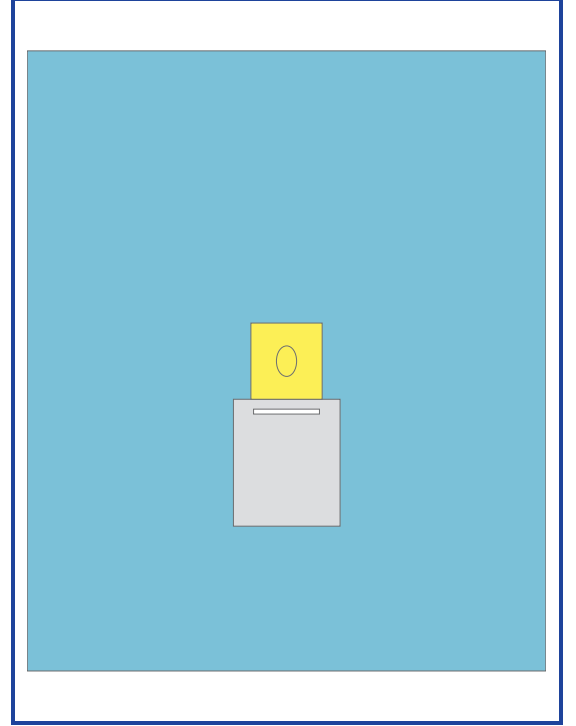


Eye Drape with Single LCP

Ref No: OSD2004060

Drape Specification:

- Fluid Repellent SMS material with high breathability, excellent conformability and resistance to tear
- 102x122 cm size
- Oval fenestrated area 6x4 cm for single eye covered with adhesive incision film 15x14 cm
- Pre attached single fluid collection pouch (21x25 cm) from high quality transparent PE material, covered flex wire on the top open edge
- Special folding for aseptic application, easy for one person to drape



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