

Declaration of Conformity

Manufacturer	:	Optimal Saglik Urunleri San. ve Dis Tic. Ltd. Sti. Firuzkoy Mah. Poyraz Cad No.100/A Mesken Apt. Avcilar – İSTANBUL / TURKEY
Product Name	:	Sterile Surgical Sets, Surgical Gowns, Surgical Drapes
Classification	:	93/42/EEC Annex IX Rule 1, Class I S
Conformity Assessment	:	93/42/EEC Annex.II.3
Standards Applied	:	ISO 13485:2012 – ISO 9001:2015 – ISO 14644-1:2015 – TS EN ISO 13795-1 :2013 – ISO 11135:2014
GMDN Code	:	33961 – Surgical Pack, Disposable 47783 – Surgical Drape, Disposable 35778 – Surgical Gown, Disposable
Notified Body	:	Kiwa Meyer Certification Services Inc.
Address	:	İTOSB 9. Cadde No:15 Tepeören Tuzla İstanbul TÜRKİYE
Notified Body No.	:	1984
EC Certificate No.	:	1984-MDD-18-521
EC Certificate Validation Date	:	17.05.2021
Start of the CE Marking	:	15.03.2018
Place, Date of Issue	:	Istanbul-TURKEY, 18.05.2018
Signature	:	Ali Alsahin President



OPTİMAL SAĞLIK ÜRÜNLERİ SANAYİ VE DİŞ TİC. LTD. ŞTİ.

Merkez & Fabrika: Firuzköy Mah, Poyraz Cad, No:100/A 34325 Avcılar - İstanbul / TÜRKİYE

Tel: +90 212 423 10 24 (Pbx) **Fax:** +90 212 423 10 25

Avcılar V.D. : 644 012 9542 **Tic. Sic. No:** 448420 / 396002

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Annex to EC Declaration of Conformity

Ref Number	Product Name
OSD2004060	EYE DRAPE WITH SINGLE LCP SMS 102X122

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