

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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