



C E R T I F I C A T E

Production Quality Assurance Medical Devices Directive 93/42/EEC Annex V

Company Name : Nurel Medikal San. ve Tic. A.Ş.

Company Address : Dosab Karanfil Sok. No:4.B. Osmangazi BURSA / TURKEY

Related Directives and Annex : 93/42/EEC Medical Devices Directive - Annex V

Product : Sterile Surgical Gowns, Surgical Drapes and Drape Sets - Class Is

GMDN : 47783, 35778, 35092

Certificate Number : M.2016.106.7196
Report Number : MD.3336.YB
Initial Assessment Date : 15.07.2016
Registration Date : 23.11.2016
Recertification Assessment Date : 02.10.2019
Reissue Date / No : 04.05.2020/01
Revision Date /No : -
Expiry Date : 27.05.2024



UDEM International Certification
Auditing Training Centre Industry
and Trade Inc. Co.



UDEM hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance audits, defined by Annex V, section 4 of the aforementioned directive. UDEM's responsibility for class I devices covered by the EC certificate is limited to manufacturing issues related to safeguarding and maintaining sterile conditions, if the device is sterile; and manufacturing issues related to product's conformity with metrological requirements, if it has measurement function. This certificate remains as the property of UDEM International Certification Auditing Training Centre Industry and Trade Inc. Co. to whom it must be returned upon request. The above named company and UDEM must keep a copy of this certificate for 5 years from the registration of the certificate. Usage of the CE mark is under the responsibility of the manufacturer with the completion of EC Declaration of Conformity. The above mentioned company must notify all changes related with the approved product to UDEM. If UDEM will not renew the expiry date of this certificate in question, the mentioned company should stop placing the product on the market. The validity of the certificate can be checked through www.udem.com.tr.

Address: Mutlukent Mahallesi 2073 Sokak (Eski 93 Sokak) No:10 Çankaya – Ankara – TURKEY
Phone: +90 0312 443 03 90 **Fax:** +90 0312 443 03 76
E-mail: info@udemltd.com.tr www.udem.com.tr



TÜRK STANDARDLARI ENSTİTÜSÜ
TÜRK STANDARDLARINA UYGUNLUK BELGESİ
TURKISH STANDARDS INSTITUTION
CERTIFICATE OF CONFORMITY TO TURKISH STANDARDS

Markanın Tanımı Description of the Mark
TSE veya/or  veya/or T S E

BELGE NUMARASI REFERENCE NUMBER OF LICENCE	032856-TSE-01/02
BELGENİN İLK VERİLİŞ TARİHİ DATE OF FIRST ISSUE OF LICENCE	27.04.2007
BELGENİN SON GEÇERLİLİK TARİHİ LICENCE VALID UNTIL	27.04.2024
BELGE SAHİBİ KURULUŞUN ADI NAME OF THE LICENCE HOLDER	NUREL MEDİKAL SANAYİ VE TİCARET A.Ş
BELGE SAHİBİ KURULUŞUN ADRESİ ADDRESS OF THE LICENCE HOLDER	DEMİRTAŞ ORGANİZE SANAYİ BÖLGESİ KARANFİL SOK. NO:4/B OSMANGAZİ BURSA/TÜRKİYE
ÜRETİM YERİ ADI NAME OF THE MANUFACTURING PLACE	NUREL MEDİKAL SANAYİ VE TİCARET A.Ş.
ÜRETİM YERİ ADRESİ ADDRESS OF THE MANUFACTURING PLACE	DEMİRTAŞ ORGANİZE SANAYİ BÖLGESİ KARANFİL SOK. NO:4/B OSMANGAZİ BURSA / TÜRKİYE
İPTAL EDİLEN BELGE NUMARASI (Varsa) INDICATION OF SUPERSEDED LICENCE (if any)	032856-TSE-01/01
TESCİLLİ TİCARİ MARKASI REGISTERED TRADE MARK	EUROSET
İLGİLİ TÜRK STANDARDI RELATED TURKISH STANDARD	TS EN 13795-1 / 30.09.2019
BELGE KAPSAMI SCOPE OF LICENCE	

HASTALAR, KLİNİK PERSONELİ VE DONANIMLAR İÇİN TIBBİ CİHAZ OLARAK KULLANILAN
CERRAHİ ÖRTÜ-YÜKSEK PERFORMANS,TEK KULLANIMLIK
CERRAHİ ÖRTÜ-STANDARD PERFORMANS,TEK KULLANIMLIK
CERRAHİ ÖNLÜK-YÜKSEK PERFORMANS,TEK KULLANIMLIK
CERRAHİ ÖNLÜK-STANDARD PERFORMANS,TEK KULLANIMLIK

e-imzalı/e-signed

04.05.2023

Belgelendirme Merkezi Başkanı Adına
ASU KORNOŞOR

TSE BURSA BELGELENDİRME MÜDÜRÜ

*Bu belge, belgelendirilen ürünün, üretim yerinin Enstitümüzün belirlediği şartları karşıladığını da gösterir.

*Bu belge, hiç bir suretle tahrif edilemez, kısmen veya okunmasını zorlaştıracak şekilde çoğaltılamaz, kazıntı ve silinti yapılamaz.

*TSE BURSA BELGELENDİRME MÜDÜRLÜĞÜ * Adres: Organize Sanayi Bölgesi Kırmızı Cad. No:6 16140 BURSA * Telefon: 02242438000(5H)* Faks: 02242438324

*TSE BELGELENDİRME MERKEZ BAŞKANLIĞI; Adres: Necatibey Cad. No:112 06100 Bakanlıklar/ANKARA – Telefon: 0 312 416 64 81 / 416 64 27, Faks:0 312 416 66 17 E-posta :bmb@tse.org.tr , web : www.tse.org.tr

