NUVO CERTIFICATION

NUVOCERT

AT SERTİFİKA / EC CERTIFICATE

EN ECZA DEPOSU İLAÇ MEDİKAL ÖZEL SAĞLIK HİZMETLERİ İNŞAAT TAAHHÜT TİCARET ANONİM ŞİRKETİ

Saray Mahallesi Gıdacılar Caddesi No:18 33020 Kahramankazan / Ankara / Türkiye

NUVO TEKNİK, YUKARIDA BELİRTİLEN ÜRETİCİNİN, TIBBİ CİHAZLAR YÖNETMELİĞİ (MDR) AB 2017/745'E GÖRE BİR KALİTE YÖNETİM SİSTEMİ UYGULADIĞINI, BU YÖNETİM SİSTEMİ YÖNETMELİĞİN SADECE BAHSİ GEÇEN ÜRÜNÜN ÜRETİMİNİN GÜVENLİK VE HİJYEN KOŞULLARINI SAĞLAMA VE DEVAM ETTİRME İLE İLGİLİ GEREKLİLİKLERİN KARŞILANDIĞINI BEYAN EDER. ONAYLANAN BU KALİTE YÖNETİM SİSTEMİ, TIBBİ CİHAZLAR YÖNETMELİĞİ (MDR) AB 2017/745'E GÖRE PERİYODİK OLARAK GÖZETİME VE HABERSİZ SAHA DENETİMLERİNE TABİDİR. ÜRETİCİ ÜRÜNLERİNİN TASARIMINDA VE YAPISINDA GERÇEKLEŞTİRDİĞİ ÖNEMLİ DEĞİŞİKLİKLERİ NUVO TEKNİK'E BİLDİRMEK ZORUNDADIR.

NUVO TECHNIC INTERNATIONAL, DECLARES THAT THE AFOREMENTIONED MANUFACTURER HAS IMPLLEMENTED A QUALITY ASSURANCE SYSTEM ACCORDING TO MEDICAL DEVICES REGULATION (MDR) EU 2017/745. THIS QUALITY ASSURANCE SYSTEM COVERS THOSE ASPECS OF MANUFACTURING CONCEMED WITH SECURING AND MAINTAINING SAFE AND HYGIENE CONDITIONS OF THE RESPECTIVE PRODUCTS AND CONFORMS TO THE PROVISIONS OF THIS DIRECTIVE. THE APPROVED QUALITY SYSTEM IS SUBJECT SURVEILLANCE MEDICAL DEVICES REGULATION (MDR) EU 2017/745 AND UNANNOUNCED AUDITS. NUVO TECHNIC, MUST BE INFORMED OF ANY SIGNIFICANT CHANGES IN THE DESIGN AND/OR PRUDUCTS.

ÜRÜN TANIMI / DESCRIPTION OF THE PRODUCT:	**EN 14683:2019+AC:2019 Type IIR MEDİKAL YÜZ MASKESİ /** MEDICAL FACE MASK
ÜRÜN MODELİ VE TİPİ / PRODUCT MODEL AND TYPE	**ENM-313 Type IIR (Siyah, Mavi, Beyaz, Yeşil, Pembe, Sarı, Desenli, Logo, Christmas/** Black, Blue, White, Green, Pink, Yellow, Patterned, Logo, Christmas)
ÜRÜNÜN TİCARİ MARKASI / PRODUCT COMMERCIAL BRAND:	**ENMED**
UYGULANABİLİR AT DİREKTİFİ/APPLICABLE EC DIRECTIVES:	**TIBBİ CİHAZLAR YÖNETMELİĞİ (MDR) AB 2017/745 /** MEDICAL DEVICES REGULATION (MDR) EU 2017/745
UYGULANABİLİR UYUMLU STANDARTLAR / APPLICABLE HARMONISED STANDARDS:	**EN 14683:2019+AC:2019 TIBBİ YÜZ MASKELERİ-GEREKLİLİKLER VE DENEY YÖNTEMLERİ /** MEDICAL FACE MASKS REQUIREMENTS AND TEST METHODS, **EN ISO 15223-1 TIBBİ CİHAZLAR–TIBBİ CİHAZ ETİKETLERİNDE, ETİKETLEMEDE VE SUNULACAK BİLGİDE KULLANILACAK SEMBOLLER /** MEDICAL DEVICES – SYMBOLS TO BE USED WITH MEDICAL DEVIDE LABELS, LABELLING AND INFORMATION TO BE SUPPLIED, **EN ISO 14971 TIBBİ CİHAZLAR–TIBBİ CİHAZLARA RİSK YÖNETİMİNİN UYGULANMASI /** MEDICAL DEVICES – APPLICATION OF RISK MANAGEMENT TO MEDICAL DEVICES, **TS EN ISO 10993-10 TIBBÎ CİHAZLARIN BİYOLOJİK DEĞERLENDİRİLMESİ-BÖLÜM 10: TAHRİŞ VE CİLT DUYARLILIĞI İÇİN DENEYLER (ISO 10993-10:2010) /** BIOLOGICAL EVALUATION OF MEDICAL DEVICES - PART 10: TESTS FOR IRRITATION AND SKIN SENSITIZATION(ISO 10993-10:2010
ÜRÜN DENEY SONUÇ RAPORLARI/ PRODUCT TEST RESULT REPORTS:	**2020/000316-IVT-SİT-724, 2020/000316-IVV-IRT-761, 2020/000316-IVV-SEN-760, 20042770, 20041685, 20027841, 20032081**

İlk Yayın Tarihi / Date of First Issue	**: 16.11.2021**
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Sertifika No / Certificate No	**: NV-CE-01-1611/21**

NUVO BELGELENDİRME MÜDÜRÜ / NUVO CERTIFICATION MANAGER

NUVOCERT

ULUSLARARASI BELGELENDİRME VE EĞİTİM HİZMETLERİ TİC. LTD. ŞTİ. Nuvo Teknik Belgelendirme NUVOCERT

CE

UYGUNLUK BEYANI
(ATTESTATION OF CONFORMITY)

Üretici Firma/Manufacturer :
EN ECZA DEPOSU İLAÇ MEDİKAL ÖZEL SAĞLIK HİZMETLERİ İNŞAAT TAAHHÜT TİCARET ANONİM ŞİRKETİ
Adres : **Saray Mahallesi Gıdacılar Caddesi No:18 33020 Kahramankazan / Ankara / Türkiye**
Tel / Fax : **+90 312 802 07 16**
Web/ E-Mail : **info@enmedglobal.com / www.enmedglobal.com**

UYGULANABİLİR AT DİREKTİFİ/APPLICABLE EC DIRECTIVES:
TIBBİ CİHAZLAR YÖNETMELİĞİ (MDR) AB 2017/745 / MEDICAL DEVICES REGULATION (MDR) EU 2017/745

UYGULANABİLİR UYUMLU STANDARTLAR / APPLICABLE HARMONISED STANDARDS:
EN 14683:2019+AC:2019 TIBBİ YÜZ MASKELERİ-GEREKLİLİKLER VE DENEY YÖNTEMLERİ / MEDICAL FACE MASKS REQUIREMENTS AND TEST METHODS, **EN ISO 15223-1 TIBBİ CİHAZLAR–TIBBİ CİHAZ ETİKETLERİNDE, ETİKETLEMEDE VE SUNULACAK BİLGİDE KULLANILACAK SEMBOLLER /** MEDICAL DEVICES – SYMBOLS TO BE USED WITH MEDICAL DEVIDE LABELS, LABELLING AND INFORMATION TO BE SUPPLIED, **EN ISO 14971 TIBBİ CİHAZLAR–TIBBİ CİHAZLARA RİSK YÖNETİMİNİN UYGULANMASI /** MEDICAL DEVICES – APPLICATION OF RISK MANAGEMENT TO MEDICAL DEVICES, **TS EN ISO 10993-10 TIBBÎ CİHAZLARIN BİYOLOJİK DEĞERLENDİRİLMESİ-BÖLÜM 10: TAHRİŞ VE CİLT DUYARLILIĞI İÇİN DENEYLER (ISO 10993-10:2010) /** BIOLOGICAL EVALUATION OF MEDICAL DEVICES - PART 10: TESTS FOR IRRITATION AND SKIN SENSITIZATION(ISO 10993-10:2010)

Bu talimatlara uygunlukla ilgili bilgiler uygunluk dosyasında belirtilmiştir.
For further information about compliance with these directivies see technical files.

ÜRÜN TANIMI / DESCRIPTION OF THE PRODUCT:
EN 14683:2019+AC:2019 Type IIR MEDİKAL YÜZ MASKESİ / MEDICAL FACE MASK

ÜRÜN MODELİ VE TİPİ / PRODUCT MODEL AND TYPE:
ENM-313 Type IIR (Siyah, Mavi, Beyaz, Yeşil, Pembe, Sarı, Desenli, Logo, Christmas/ Black, Blue, White, Green, Pink, Yellow, Patterned, Logo, Christmas)

ÜRÜN DENEY SONUÇ RAPORLARI/ PRODUCT TEST RESULT REPORTS:
2020/000316-IVT-SİT-724, 2020/000316-IVV-IRT-761, 2020/000316-IVV-SEN-760, 20042770, 20041685, 20027841, 20032081

Ürünün Ticari Markası / *Product commercial brand* : **ENMED**

Tanımlanan ürünler yukardaki Avrupa Normlarının talimatlarına uygundur.
The designated products conform to the provisions of the above european directives

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This declaration certifies compliance with the indicated directives but İmpliens no warranty of properties. All safety instructions shown on products documentation and mounting ıinstructions etc. Shall be coserved.

Sertifika No / *Certificate number* : ANK2021/16.11-001– Rev: 00
İlk Yayınlanma Tarihi / *Date of First Issue* : 16.11.2021
Yenileme Tarihi / *Reissue Date* : 15.11.2022

MERSİN/ TURKEY – 16.11.2021
Yetkili İmza / *Legally Binding Signature*

Certificate of Registration
2021

This is to certify that the registration of

EN ECZA DEPOSU ILAC OZEL SAGLIK HIZ. INS. TAH. A.S.
KARADUVAR MAH. SERBEST BOLGE 11. CAD. NO:23 AKDENIZ
MERSIN, TURKEY- 33200

with U.S. Food and Drug Administration as required by 21 CFR Part 807 is successfully completed by Liberty Management Group Ltd with the information provided by En Ecza Deposu Ilac Ozel Saglik Hiz. Ins. Tah. A.S.

Registration Number	**3017010911**
Date of Renewal	**October 4, 2020**
Date of Expiration	**December 31, 2021**
US Agent	**Liberty Management Group Ltd.**
Device Listing Numbers	**See Annex**
Certificate Number	**3010040220**

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LMG LIBERTY MANAGEMENT GROUP LTD.
75 Executive Drive, Aurora, Illinois, USA
www.fdahelp.us

Manoj Zacharias
President
Liberty Management Group LTD.
Dated: December 3, 2020

Certificate of Registration
2021

Annex - Device Listings

Listing Number	Code	Device Name - Proprietary Names
D403117	FXO	Suit, Surgical - ENMED suit
D403116	OEA	Non-Surgical Isolation Gown - ENMED Isolation Gown
D403114	QKR	Face mask (except N95 respirator) for general public/healthcare personnel per IIE guidance - ENMED FACE MASK
D403115	FME	Gown, examination - ENMED Examination gown
D403119	FYF	Cap, Surgical - ENMED CAP
D403118	FXP	Cover, Shoe, Operating-Room - ENMED shoe cover