

Prophylactic

Prophylactic protective shoe

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CE UYGUNLUK BEYANI

CE ATTESTATION OF CONFORMITY

BOINC TEKSTİL SANAYİ VE TİCARET LİMİTED ŞİRKETİ

Beştelsiz Mahallesi Semiha Şakir Caddesi No:63/67 Zeytinburnu İSTANBUL / TURKEY

In our delivered version, we declare that the product described below complies with the essential safety and health requirements of the Personel Medical Devices Directive 93/42/EEC-General Product Safety Directive 2001/95/EEC regulations as circulating by us. This declaration will cease to be valid if the product specified below is replaced.

Teslim edilen versiyonumusda aşağıda açıklanan ürünün, tarafimuda dolaşıma sokulduğu şekliyle Tibbi Cihazlar Direktifi 93/42/EEC-Genel Ürün Güvenliği Direktifi 2001/95/EEC yönetmeliklerini tenel güvenlik ve sağlık gerekliliklerine uygan olduğunu beyan ederiz. Aşağıda bilgileri belirilen ürünün değiştirilmesi halinde bu beyan geçerliliğini yittrecekur.

Description Of The Product Ürünün Tanımı

: DISPOSABLE PROTECTIVE CLOTHING TEK KULLANIMLIK KORUYUCU AMAÇLI GİYSİLER

Product Commercial Brand / Marka: PROPHYLACTIC

Applicable EC Directives

: GENERAL PRODUCT SAFETY DİRECTİVE 2001/95/EEC

MEDICAL DEVICES DIRECTIVE 93/42/EEC GENEL ÜRÜN GÜVENLIĞI DİREKTİFİ 2001/95/EEC TIBBİ CİHAZLAR DİREKTİFİ 93/42/EEC

Geçerli AT Direktifleri

Applicable Harmonised Standards : EN ISO 13982-1/A1, EN 14126, EN 1073-2, EN 1149-1, EN 1149-5, Geçerli Uyumlaştırılmış Standarılar EN 13034, EN 14605

Applicable National Technical Standards and Specifications Uggulanobilir Ulusul Teknik Standardar ve Özellikler Classifications / Singlandarma Certificate Number / Sertifika Numarası

Certificate Code / Sertifika Kodu Certificate Issue Date / Sertifika Yayın Tarihi

Certificate Validity Date / Sertifikanın Geçerlilik Tarihi EU Representative / AB Temsilcisi (Authorized Signature and Title) / (Yetkili İmza ve Ünvan)

: CLASS-I : 20041509

: YENÎ KAYATÜRK : 15.04.2020

: 15.04.2021

YENÎ KAYATÜRK GIDA ÎNS. TEKS. TARÎM ÎTH. ÎHR. ÜRETÎM SAN. TÎC, A.S. declares that the Medical De 3342/EEC-General Product Safety Directive 2001/95/EEC has fulfilled the applicable requirements and responsible the above-described product groups. The product groups described above have been controlled depending on intern

YENÎ KAVATÜRK GIDA ÎNŞ. TEKS. TARIM ÎTH. ÎHR. ÜRETÎM SAN. TÎC. A.Ş. olarak yakurda tanındarmış olan tetin gruşdari için Tibbi Chazları Direktif 98-42 ESC-Genel Ürus Gürenliği Direktif 2001.95 ESC 'nin upşalansıblın gerekliliklerin yerine getirdiğini ve vonunlukğun almanşı olandığının beyan etinekticin. Fikarıfak tanındının itrisi gruşdar, iş teetim kortlerine bağlı örterid olüning

www.nvakalite.com info@nvakalite.com



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CERTIFICATE OF REGISTRATION



This Certificate has been awarded to

BOİNC TEKSTİL SANAYİ VE TİCARET LIMİTED ŞİRKETİ

BEŞTELSİZ MAHALLESİ SEMİHA ŞAKİR CADDESİ. NO:63/67 Zeytinburnu ISTANBUL/TÜRKİYE

> In recognition of the organization's Management System which complies with

> > ISO 45001:2018(OHSMS)

The scope of activities covered by this certificate is defined below

PRODUCTION AND SALES OF PROTECTIVE MASK FROM WASHABLE FABRIC, GLOVES, GOWNS, FACE AND EYE PROTECTIVE, PROTECTIVE BAG, SLEEPING MASK, HAIR BONETTE FOR POOL, POOL EYE-PROTECTIVE, DISPOSABLE NONWOVEN MASK, SINGLE-USE TULUM, PROTECTIVE EN 095, EN 096, EN 097 MASKS AND ALL KINDS OF TEXTILE PRODUCTS

YIKANABİLİR KUMAŞTAN KOR<mark>UYUCU MASKE, ELDİVEN, ÖNL</mark>ÜK, YÜZ VE GÖZ KORUYUCU, KORUYUCU TULUM, UYKU MASKESİ, HAVUZ İÇİN SAÇ BONESİ, HAVUZ İÇİN GÖZ KORUYUCU, TEK KULLANIMLIK NONWOVEN MASKE, TEK KULLANIMLIK TULUM, KORUYUCU EN 095, EN 096, EN 097 MASKELER VE HER TÜRLÜ TEKSTİL ÜRÜNLERİ ÜRETİMİ VE SATIŞI

Certificate Number: SISTURO042020348 Date of Issue of Original Certificate: 18.04.2020 Date of Issue of latest certificate: 18.04.2020 Expiry Date: 17.04.2021



continuation letter after the surveillance is carried out successfully.



Corporate office(SIS):- Plot No. 1539, 2nd Floor, Sector-4, Gurgaon-122001, Haryana, India. International office(SIS):- URB. Santa Ana Cal. German, Scherieber 276, San Isidro, Lima, Peru 15047. Email us :-support@siscertifications.com, info@siscertifications.co.in, Call:- +91-9554721646 Web:- http://www.siscertifications.co.in, www.siscertifications.com The status of this certificate can be verified on "http://www.siscertifications.co.in".

Issue No.: 01





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SERTIFICATE OF REGISTRATION



This Certificate has been awarded to

BOİNC TEKSTİL SANAYİ VE TİCARET LİMİTED ŞİRKETİ

BEŞTELSİZ MAHALLESİ SEMİHA ŞAKİR CADDESİ. NO:63/67 Zeytinburnu İSTANBUL/TÜRKİYE

In recognition of the organization's Management System which complies with

ISO 14001:2015(EMS)

The scope of activities covered by this certificate is defined below

PRODUCTION AND SALES OF PROTECTIVE MASK FROM WASHABLE FABRIC, GLOVES, GOWNS, FACE AND EYE PROTECTIVE, PROTECTIVE BAG, SLEEPING MASK, HAIR BONETTE FOR POOL, POOL EYE-PROTECTIVE, DISPOSABLE NONWOVEN MASK, SINGLE-USE TULUM, PROTECTIVE EN 095, EN 096, EN 097 MASKS AND ALL KINDS OF TEXTILE PRODUCTS

YIKANABİLİR KUMAŞTAN KORUYUCU MASKE, ELDİVEN, ÖNLÜK, YÜZ VE GÖZ KORUYUCU, KORUYUCU TULUM, UYKU MASKESİ, HAVUZ İÇİN SAÇ BONESİ, HAVUZ İÇİN GÖZ KORUYUCU, TEK KULLANIMLIK NONWOVEN MASKE, TEK KULLANIMLIK TULUM, KORUYUCU EN 095, EN 096, EN 097 MASKELER VE HER TÜRLÜ TEKSTİL ÜRÜNLERİ ÜRETİMİ VE SATIŞI

Certificate Number: SISTURE042020800 Date of Issue of Original Certificate: 18.04.2020 Date of Issue of latest certificate: 18.04.2020 Expiry Date: 17.04.2021









Note: This certificate is valid only if produced with the continuation letter after the surveillance is carried out successfully.



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Issue No.: 01

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SERTIFICATE OF REGISTRATION



This Certificate has been awarded to

BOİNC TEKSTİL SANAYİ VE TİCARET LİMİTED ŞİRKETİ

BEŞTELSİZ MAHALLESİ SEMİHA ŞAKİR CADDESİ.NO:63/67 Zeytinburnu **ISTANBUL/TÜRKİYE**

> In recognition of the organization's Management System which complies with

> > ISO 45001:2018(OHSMS)

The scope of activities covered by this certificate is defined below

PRODUCTION AND SALES OF PROTECTIVE MASK FROM WASHABLE FABRIC, GLOVES, GOWNS, FACE AND EYE PROTECTIVE, PROTECTIVE BAG, SLEEPING MASK, HAIR BONETTE FOR POOL, POOL EYE-PROTECTIVE, DISPOSABLE NONWOVEN MASK, SINGLE-USE TULUM, PROTECTIVE EN 095, EN 096, EN 097 MASKS AND ALL KINDS OF TEXTILE PRODUCTS

YIKANABİLİR KUMAŞTAN KO<mark>RUYUCU MASKE, ELDİVEN, ÖNLÜK, Y</mark>ÜZ VE GÖZ KORUYUCU, KORUYUCU TULUNI, UYKU MASKESİ, HAVUZ İÇİN SAÇ BONESİ, HAVUZ İÇİN GÖZ KORUYUCU, TEK KULLANIMLIK NONWOVEN MASKE, TEK KULLANIMLIK TULUM, KORUYUCU EN 095, EN 096, EN 097 MASKELER VE HER TÜRLÜ TEKSTİL ÜRÜNLERİ ÜRETİMİ VE SATIŞI

Certificate Number: SISTURO042020348 Date of Issue of Original Certificate: 18.04.2020 Date of Issue of latest certificate: 18.04.2020 Expiry Date: 17.04.2021









The Organization's documentation and Implementation has been reviewed and found to comply with the relevant standard rules. This certificate of Registration is based on the evaluation of the mentioned scope given above. Organization is responsible for maintaining the responsibilities of the relevant standard rules. Any significant changes in the scope of the certification or standard referred above render this certificate invalid. This is an accredited certificate issued by SIS Certifications Pvt. Ltd. sanctioned for issue by International Accreditation Services , 3060 Saturn Street Suite 100 Brea, California 92821-1732, USA.

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CERTIFICATE

of Registration



This is to Certify that the Medical Devices – Quality Management System

of

BOİNC TEKSTİL SANAYİ VE TİCARET LİMİTED ŞİRKETİ

BEŞTELSİZ MAHALLESİ SEMİHA ŞAKİR CADDESİ.NO:63/67 Zeytinburnu İSTANBUL/TÜRKİYE

has been independently assessed and is compliant with the requirements of

ISO 13485:2016

This Certificate is applicable to the following product or service ranges:

PROTECTIVE MASK FROM WASHABLE FABRIC, GLOVES, GOWNS, FACE AND EYE PROTECTIVE, PROTECTIVE BAG, SLEEPING MASK, HAIR BONETTE FOR POOL, POOL EYE-PROTECTIVE, DISPOSABLE NONWOVEN MASK, SINGLE-USE TULUM, PROTECTIVE EN 095, EN 096, EN 097 MASKS AND ALL KINDS OF TEXTILE PRODUCTS PRODUCTION AND SALES

YIKANABİLİR KUMAŞTAN KORUYUCU MASKE, ELDİVEN, ÖNLÜK, YÜZ VE GÖZ KORUYUCU, KORUYUCU TULUM, UYKU MASKESİ, HAVUZ İÇİN SAÇ BONESİ, HAVUZ İÇİN GÖZ KORUYUCU, TEK KULLANIMLİK NONWOVEN MASKE, TEK KULLANIMLİK TULUM, KORUYUCU EN 095, EN 096, EN 097 MASKELER VE HER TÜRLÜ TEKSTİL ÜRÜNLERİ ÜRETİMİ VE SATIŞI

:: Certificate No :: TR51971H

Date of initial registration 18 April 2020

Date of this Certificate 18 April 2020

Surveillance audit on or before 17 April 2021

Recertification Due / Certificate expiry 17 April 2023
This Certificate is property of Staunchly Management & System Services Ltd. and remains valid

Director





STAUNCHLY MANAGEMENT & SYSTEM SERVICES LTD.
Suite 48, 88-90 Hatton Garden, London, EC1N 8PN

Phone: +44 345 680 0199

Email: info@staunchlyservices.com Web: www.staunchlyservices.com

For precise and updated information concerning the present certificate mail to info@staunchlyservices.com

This Certificate is the property of Staunchly Management & System Services Private Limited and shall be returned immediately when demande