

Sertifika

certificate

CERTIFICATE of CONFORMITY

APPLICANT : SONİK MAKİNA SANAYİ VE TİCARET LTD.ŞTİ.

HASTANE MAH. MEHMET AKİF ERSOY CAD. NO: 14 İÇ KAPI NO: 1 ARNAVUTKÖYÜ İSTANBUL

MANUFACTURER : SONİK MAKİNA SANAYİ VE TİCARET LTD.ŞTİ.

HASTANE MAH. MEHMET AKİF ERSOY CAD. NO: 14 İÇ KAPI NO: 1 ARNAVUTKÖYÜ İSTANBUL

Product Name : 3 LAYERS SURGICAL MASK (FILTERED-UNFILTERED)

Product Classification : Class I

Applied Directive(s) : 93/42/EEC Medical Device Directive

This certificate has been issued according to the voluntary application of the manufacturer. This certificate is valid only for the product(s) in above mentioned. This certificate confirms that the declaration of conformity which is prepared by manufacturer is available. It's manufacturer's sole responsibility to meet all the necessary conformity assessment activities according to 93/42/EEC Medical Devices Directive and related standards or the mentioned product(s) before placing them on the market. It is the manufacturer's responsibility to comply a full technical file according to Annex VII of 93/42/EEC and the manufacturer is the responsible to take all necessary actions before affixing **CE** mark on the product(s)

Date of issue of this certificate : 07.03.2022

Expiry date : 06.03.2023

Certificate Number : 22.01.301-CE



CE


Genel Müdür
General Manager

Inspect Uluslararası Belgelendirme ve Gözetim Hizmetleri Tic. Ltd. Şti. / TURKEY
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Client Name and address:

Müşteri ismi ve adresi

SONİK MAKİNA SANAYİ VE TİCARET LTD.ŞTİ.

HASTANE MAH. MEHMET AKİF ERSOY CAD. NO: 14 İÇ KAPI NO: 1 ARNAVUTKÖY/ İSTANBUL

Standard

Standard

ISO 13485:2016 Quality Management Systems-Medical Devices

INSPECT assessed and approved that related firm meets the requirements of the designated standard at related scope
INSPECT ilgili kuruluşun yukarıda belirtilen standardın gereklerine uygunluğunu ilgili kapsamda tetkik etmiş olup onaylamaktadır.

Scope

Kapsam

BAĞCIKLI CERRAHİ MASKE, ÇOCUK YÜZ MASKESİ, TELA GALOŞ, POLİETİLEN GALOŞ, TELA KOLLUK, POLİETİLEN KOLLUK, SPUNBOND TULUM, LAMİNELİ TULUM, SPUNBOND BONE, DUŞ BONESİ, MANİKÜR BONESİ, PEDİKÜR GALOŞ, KOLONOSKOPİ ŞORTU, KİŞİSEL KORUYUCU ÖNLÜK, CERRAHİ ÖNLÜK, SPUNBOND SEDYE ÖRTÜSÜ, POLİETİLEN SEDYE ÖRTÜSÜ VE STERİL SET VE ÖRTÜ ÜRÜNLERİ ÜRETİMİ VE SATIŞI

MANUFACTURING AND SELLING OF LACED MASK, CHILD FACE MASK, BUCKRAM OVERSHOE, POLYETHYLENE OVERSHOE, BUCKRAM OVERSLEEVE, POLYETHYLENE OVERSLEEVE, SPUNBOND OVERALL, LAMINATED OVERALL, SPUNBOND BONET, SHOWER BONET, MANICURE BONET, PEDICURE OVERSHOE, COLONOSCOPY SHORTS, PERSONNEL PROTECTIVE APRON, SURGICAL APRON, SPUNBOND STRETCHER COVER, POLYETHYLENE STRETCHER COVER AND STERILE SET AND COVER PRODUCTS

EA/Category Code: A

Initial issue date: 07.Mar.2022

Issue date of this certificate: 07.Mar.2022

Validity of this certificate: 06.Mar.2023

Recertification date: 06.Mar.2025

Certificate No: 22.01.301-MD

To verify the validity of this certificate please visit: www.inspect.com.tr

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Date: 2022.04.08 12:02:44 ESTs depend on the results of surveillance assessments

Reason: Mold Sign Signature

Location: Moldova



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www.inspect.com.tr - Belge periyodu 3 yıldır. / Certificate period is 3 years.



Inspect

Certificate
Sertifika

Client Name and address

Müşteri ismi ve adresi

SONİK MAKİNA SANAYİ VE TİCARET LTD.ŞTİ.

HASTANE MAH. MEHMET AKİF ERSOY CAD. NO: 14 İÇ KAPI NO: 1 ARNAVUTKÖY/ İSTANBUL

Standard

Standard

ISO 9001:2015

Quality Management System

INSPECT assessed and approved that related firm meets the requirements of the designated standard at related scope
INSPECT ilgili kuruluşun yukarıda belirtilen standardın gereklerine uygunluğunu ilgili kapsamda tetkik etmiş olup onaylamaktadır.

Scope

Kapsam

BAĞCIKLI CERRAHİ MASKE, ÇOCUK YÜZ MASKESİ, TELA GALOŞ, POLİETİLEN GALOŞ, TELA KOLLUK, POLİETİLEN KOLLUK, SPUNBOND TULUM, LAMİNELİ TULUM, SPUNBOND BONE, DUŞ BONESİ, MANİKÜR BONESİ, PEDİKÜR GALOŞ, KOLONOSKOPI ŞORTU, KİŞİSEL KORUYUCU ÖNLÜK, CERRAHİ ÖNLÜK, SPUNBOND SEDYE ÖRTÜSÜ, POLİETİLEN SEDYE ÖRTÜSÜ VE STERİL SET VE ÖRTÜ ÜRÜNLERİ ÜRETİMİ VE SATIŞI

MANUFACTURING AND SELLING OF LACED MASK, CHILD FACE MASK, BUCKRAM OVERSHOE, POLYETHYLENE OVERSHOE, BUCKRAM OVERSLEEVE, POLYETHYLENE OVERSLEEVE, SPUNBOND OVERALL, LAMINATED OVERALL, SPUNBOND BONET, SHOWER BONET, MANICURE BONET, PEDICURE OVERSHOE, COLONOSCOPY SHORTS, PERSONNEL PROTECTIVE APRON, SURGICAL APRON, SPUNBOND STRETCHER COVER, POLYETHYLENE STRETCHER COVER AND STERILE SET AND COVER PRODUCTS

EA/Category Code: 04-14

Initial issue date: 07.Mar.2022

Issue date of this certificate: 07.Mar.2022

Validity of this certificate: 06.Mar.2023

Recertification date: 06.Mar.2025

Certificate No: 22.01.301-QM

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General Manager

ACCREDITED
Management System
Certification Body
MSCB 146