



MAKSİMED
TEK KULLANIMLIK ÜRÜNLER

www.maksimed.com.tr

DECLARATION OF CONFORMITY

Company Name: Sonik Makina Sanayi ve Ticaret Ltd.Şti.
Address: Yeşilçe Mah. Büyükdere Sk. No:30/A Kağıthane / İstanbul
Tel: +90 212 381 24 28
Fax: +90 212 381 24 22
Web: www.sonikmakina.com.tr
E-mail: info@sonikmakina.com

Product Name	Reference No.	Classification	CE/EN Code
Özel Fiyat (Personalized)	204502	Class I (Type I)	9007

Conformity Assessment Procedure: Annex V

We herewith declare on our own responsibility that the product mentioned meets the provisions of the CE Marking Directive and complies with the CE Marking for Medical Device Directive.



City: Çekirge - İstanbul, 17/04/2021
Name: Yalçın Kaşgarcı
Position: General Manager
SIGNATURE



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City: Çekirge - İstanbul, 17/04/2021
Name: Yalçın Kaşgarcı
Position: General Manager
SIGNATURE



SONİK MAKİNA SANAYİ VE TİCARET LTD. ŞTİ.

YERLİCE MAH. BÜYÜKDERE SK. NO:30/A KAĞITHANE / İSTANBUL / TÜRKİYE

Yabancılar için verilen, ilgili ürünün Avrupa'daki ulusal düzenlemelere uyumlu ve uygulanabilirliği doğrultusunda uyulduğu ve Avrupa'da pazarlanabilir olduğunu gösteren belge. / This certificate is issued to certify that the product complies with the CE Marking Directive and complies with the CE Marking for Medical Device Directive.

ISO 45001:2018

İş Sağlığı ve Güvenliği Yönetim Sistemi

Occupational Health and Safety Management System

SEYİRCİ YOLU

MÜHÜRLEME ÜRÜNLERİ, BOMBE, TULUM, GALOŞ, EL DUVAR, ÇEKEY TORBA VE TEK KULLANIMLIK YÜZ MASKESİ ÜRETİM VE SATIŞI / PRODUCTION, SALES OF PERSONAL PROTECTIVE EQUIPMENT, BOMBS, OVERALL, OVERSHOE, GLOVES, DEAD BODY BAG AND DISPOSABLE FACE MASK

As a company, we hereby declare on our own responsibility that the product mentioned meets the provisions of the CE Marking Directive and complies with the CE Marking for Medical Device Directive.

The certificate is valid for the period of 3 years from the date of issue of the certificate. / The certificate is valid for the period of 3 years from the date of issue of the certificate.

Registration Number	CE/EN Code	Issue Date	Valid Until
01/2021/0001	9007	17.04.2021	17.04.2024

Signature: Yalçın Kaşgarcı
Position: General Manager



CERTIFICATE OF REGISTRATION



SONİK MAKİNA SANAYİ VE TİCARET LİMİTED ŞİRKETİ

YERLİCE MAH. BÜYÜKDERE SK. NO:30/A KAĞITHANE / İSTANBUL / TÜRKİYE

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

ISO 9001:2015

The scope of activities covered by the certificate is defined below:

PRODUCTION AND SALES OF PERSONAL PROTECTIVE EQUIPMENT, BOMBS, OVERALL, OVERSHOE, GLOVES, DEAD BODY BAG AND DISPOSABLE FACE MASK

KİŞİSEL KORUYUCU ÜRÜNLER, BOMBE, TULUM, GALOŞ, EL DUVAR, ÇEKEY TORBA VE TEK KULLANIMLIK YÜZ MASKESİ ÜRETİM VE SATIŞI

Certificate Number: SİS/001/2021/001
Date of issue of Original Certificate: 20.07.2021
Date of issue of Latest Certificate: 20.07.2021
Expiry Date: 20.07.2023

Signature: Yalçın Kaşgarcı
Position: Managing Director

Note: This certificate is valid only if produced with the conditions set out in the certificate and is not transferable.

The Organization's commitment and implementation has been reviewed and found to comply with the requirements of the certificate. / The certificate is issued on the basis of the information provided by the organization. / The certificate is issued on the basis of the information provided by the organization. / The certificate is issued on the basis of the information provided by the organization.

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CERTIFICATE of Registration

This is to certify that the Medical Device - Quality Management System

SONİK MAKİNA SANAYİ VE TİCARET LİMİTED ŞİRKETİ

YERLİCE MAH. BÜYÜKDERE SK. NO:30/A KAĞITHANE / 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: PRODUCTION AND SALES OF PERSONAL PROTECTIVE EQUIPMENT, BOMBS, OVERALL, OVERSHOE, GLOVES, DEAD BODY BAG AND DISPOSABLE FACE MASK

KİŞİSEL KORUYUCU ÜRÜNLER, BOMBE, TULUM, GALOŞ, EL DUVAR, ÇEKEY TORBA VE TEK KULLANIMLIK YÜZ MASKESİ ÜRETİM VE SATIŞI

Certificate No.: TRS210001
Date of initial registration: 29 July 2020
Date of this Certificate: 29 July 2021
Next review date on or before: 19 July 2022
Renewal date / Certificate expiry: 19 July 2023

Signature: Yalçın Kaşgarcı
Position: Director



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YERLİCE MAH. BÜYÜKDERE SK. NO:30/A KAĞITHANE / İSTANBUL / TÜRKİYE

Referenced Product: Medical Device (Type I)

Class: Class I

Standard: EN 9553

Regulation, Annex 1, CE Marking Standards EN 9553-1:2019, EN 9553-2:2019, EN 9553-3:2019

Declaration of Product: Disposable Face Mask

Approved by: TRB
Approved date: 17.07.2021
Valid until: 17.07.2023
Issuing No: 001

Signature: Yalçın Kaşgarcı
Position: General Manager



YERLİCE MAH. BÜYÜKDERE SK. NO:30/A KAĞITHANE / İSTANBUL / TÜRKİYE

Referenced Product: Medical Device (Type I)

Class: Class I

Standard: EN 9553

Regulation, Annex 1, CE Marking Standards EN 9553-1:2019, EN 9553-2:2019, EN 9553-3:2019

Declaration of Product: Disposable Face Mask

Approved by: TRB
Approved date: 17.07.2021
Valid until: 17.07.2023
Issuing No: 001

Signature: Yalçın Kaşgarcı
Position: General Manager





LASTİKLİ MASKE
ELASTICED MASK
MELTBLOWN FILTER
TECHNOLOGY



BAĞCIKLI MASKE
LACED MASK
MELTBLOWN FILTER
TECHNOLOGY



**FFP2 - FFP3
YÜZ MASKESİ**
FFP2 - FFP3
FACIAL MASK



ÇOCUK MASKESİ
KIDS MASK
MELTBLOWN FILTER
TECHNOLOGY



**TEK KULLANIMLIK
ÖNLÜK**
DISPOSABLE SMOCKS
SMS - SS



SEDYE ÖRTÜSÜ
STRETCHER COVER



**LAMİNELİ SEDYE
ÖRTÜSÜ**
STRETCHER COVER
LAMINATION



NİTRİL ELDİVEN
NITRILE GLOVE
LATEX ELDİVEN
LATEX GLOVE



**DIŞCI HASTA
ÖNLÜĞÜ**
DENTAL PATIENT
COVER



**DIŞ UNIT
SETİ**
DENTAL UNIT
COVER



DUŞ BONESİ
SHOWER BONET



PEDİKÜR GALOŞU
PEDICURE OVERSHOES



CERRAHİ ŞAPKA
SPUNBOND CAP



FERMUARLI TULUM
ZIPPERED OVERALLS



GALOŞ
OVERSHOE



KOLLUK
OVERSLEEVE




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