INTERNATIONAL FIRST CERTIFICATION

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SERTİFİKA

Bu Sertifika,

MHM KONFEKSİYON GIDA TEMİZLİK MADDELERİ MEDİKAL İNŞAAT MALZEMELERİ SANAYİ VE TİCARET LİMİTED ŞİRKETİ

Cumhuriyet Mahallesi Süleyman Vahit Caddesi No:67/A Yüreğir/Adana

kuruluşunun,

Maske (Muayene, Toz, Partüküllü Toz, Ağız Koruyucu, Tek Kullanımlık, Ventil Yüksek Koruma Sıvı ve Bakteri Geçirmez Yıkanabilir Ağız için) Kep, Bone, Galoş, Eldiven, Önlük, Cerrahi Yüz Maskesi, Hasta ve Ziyaretçi Önlükleri, Ameliyat Önlükleri, Masa Örtüsü, Dış Ünite Tabla Örtüsü, Sedye Örtüsü, Tulum (Hasta Tek Kullanımlık, Güvenli Çalışanlar için) Dispanser, Steril Malzemelerin ve Dezenfektanların İmalatı, Alımı, Satımı, İthalat ve İhracatı

kapsamında,

ISO 9001:2015

Kalite Yönetim Sistemi Standardının şartlarına uyan bir yönetim sistemi kurduğunu ve uyguladığını onaylamak üzere verilmiştir.

İlk Yayın Tarihi	: 25.03.2020
Yayın Tarihi	: 25.03.2020
Sertifika Geçerlilik Tarihi	: 3 Yıl/ 24.03.2023
Sertifika Bitiş Tarihi	: 24.03.2021
Sertifika No	: IFC-Q-3-20-I-3561

IAF

IAS ACCREDITED Management Systems Certification Body

MSCB-170-3561

5.1.2e

IFC GLOBAL SERTİFİKASYON MUAYENE VE EĞİTİM HİZMETLERİ ANONİM ŞİRKETİ
Adalet Mah. Manas Blv. No:39/2203 - Folkart Towers Bayraklı, İzmir, TÜR
Yeşiloba Mahallesi 46075 Sokak No:1/23 Seyhan, Adana, TÜRKİYE T:
5.1.2e ifcglobal.com.tr
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CERTIFICATE

This certificate is granted to the organization,

MHM KONFEKSIYON GIDA TEMIZLIK MADDELERI MEDIKAL INSAAT MALZEMELERI SANAYI VE TICARET LIMITED SIRKETI

Cumhuriyet Mahallesi Süleyman Vahit Caddesi No:67/A Yüreğir, Adana, TURKEY

Manufacture, Purchase, Sale, Importand Export of Mask (for Examination, Powder, Particulate Powder, Mount Powder, Mount Protector, Disposable, High Protection Valve, Liguid and Bacteria Proof Washable Mouth)Cap ,Bone, Soe Covers, Gloves, Apron, Surgical Facemask, Patient and Visitor Gowns, Surgical Gowns, Tablecloth, Dental Unit Tray Cover, Stretcher Cover, Overalls (for Patients, Disposable, Safe Workers) Dispansary, Sterile Materials and Disinfectants

according to the scope,

ISO 9001:2015

to certify that quality management system in accordance with standard's clauses is established and being implemented.

Date of First Issue	: 25.03.2020
Date of Issue	: 25.03.2020
Certificate Period	: 3 Year/ 24.03.2023
Reissue Date	: 24.03.2021
Certificate No	: IFC-Q-3-20-I-3561

IAF IAS ACCREDITED Management Systems Certification Body MSCB-170-3561

S[redacted] e Approved

5.1.2e

IFC GLOBAL SERTİFİKASYON MUAYENE VE EĞİTİM HİZMETLERİ ANONİM ŞİRKETİ
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Yeşiloba Mahallesi 46075 Sokak No:1/23 Seyhan, Adana, TÜRKİYE T: [redacted]
5.1.2e ifcglobal.com.tr

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ZEAL

EC – DECLARATION *of* CONFORMITY

UYGUNLUK BEYANI

İmatçı Manufacturer	:	**MHM KONFEKSIYON GIDA TEMIZLIK MADDELERI MEDIKAL INS. MAL. SAN. VE TIC. LIMITED SIRKETI**
Adres Address	:	Cumhuriyet Mahallesi Süleyman Vahit Caddesi No:67/A Yüreğir, Adana, TURKEY
Tel / Fax	:	5.1.2e 5.1.2e @hotmail.com
Kapsam In accordance with	:	**Tıbbi Cihaz Yönetmeliği 93/42/AT** Medical Devices Directive 93/42/ECC
Standart Standards	:	**EN 14683+AC:2019**
Brand Marka	:	**ZEAL**

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

Ürün Product	:	**Tek Kullanımlık Cerrahi Maske** Disposable Surgical Mask
Model Type	:	**MHM001- Two-Layer Mask** **MHM002- Three-Layer Mask**
Sınıf Classification	:	**Sınıf 1 (steril ve ölçme fonksiyonu olmayan)** Class 1 Anex VII (Non-Steril)
GMDN No	:	35177

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

İşbu beyan belirtilen talimatlara uygunluğu belgeler, özellikler ile ilgili garanti hakkı içermez.
Ürünle birlikte verilen tüm güvenlik uyarıları, montaj ve işletim talimatlarına uyulması gerekir.
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.

5.1.2e : 5.1.2e

Sertifika No :MHN 01 01 / 03-20 – REV: 00
Certificate number
Tarih / Date : :26.03.2020

ADANA – TURKEY 26.03.2020
5.1.2e Legally Binding Signature

MHM KONFEKSİYON
GIDA T... TD. ŞTİ.
Cu... Z01
Tel:... ANA
Yüreğ... 72421
5.1.2e

CE

INTERNATIONAL FIRST CERTIFICATION

IFC GLOBAL

INTERNATIONAL FIRST CERTIFICATION

CERTIFICATE OF CONFORMITY

We hereby declare, Manufacturer, Distributor/EU Representative:

MHM KONFEKSIYON GIDA TEMIZLIK MADDELERI MEDIKAL INSAAT MALZEMELERI SANAYI VE TICARET LIMITED SIRKETI

Cumhuriyet Mahallesi Süleyman Vahit Caddesi No:67/A Yüregir, Adana, TURKEY

that the following described product in our delivered version complies with appropriate basic safety and health requirements of the 93/42/EEC Medical Device Directive (Class I Anex VII) based on its design and type, as brought into circulation by us In Case of the alteration of the product, not agreed upon by us, this declaration will lose its validity.

Description of the Product	: NON STERILE DISPOSABLE SURGICAL FACE MASK
Model of Product	: MHM001- Two Layer Mask MHM002- Three Layer Mask
Product Commercial Brand	: ZEAL
Applicable EC Directives	: 93/42/EEC Medical Device Directive
Harmonized Standards	: EN 14683+AC:2019
Test Report No/Issue	: TSN2003018-24.03.2020/IFCGLOBAL LAB
Classification	: Class I Anex VII (Non-Steril)

IFC GLOBAL INTERNATIONAL FIRST CERTIFICATION

Issue date	: 24.03.2020
Valid from	: 24.03.2020
Valid til	23.03.2021
Certific	MCE.20.303

5.1.2e

S Approved

CE

cation Inspection & Training Services GmbH
Hohenzollernring 50, 50672 COLOGNE
5.1.2e ifcglobal.de

IFCGLOBAL
Certification Inspection &
Training Services GmbH

TEST REPORT

Industrial / Medical Services

APPLICANT	Name	MHM KONFEKSIYON GIDA TEMIZLIK MADDELERI MEDIKAL INS. MAL. SAN. VE TIC. LIMITED SIRKETI				
	Address	Cumhuriyet Mahallesi Süleyman Vahit Caddesi No:67/A Yüreğir, Adana, TURKEY				
	Tel	5.1.2e	Fax	5.1.2e	E-Mail	5.1.2e @hotmail.com

MANUFACTURER	Name	MHM KONFEKSIYON GIDA TEMIZLIK MADDELERI MEDIKAL INS. MAL. SAN. VE TIC. LIMITED SIRKETI				
	Adress	Cumhuriyet Mahallesi Süleyman Vahit Caddesi No:67/A Yüreğir, Adana, TURKEY				
	Tel	5.1.2e	Fax	5.1.2e	E-Mail	5.1.2e @hotmail.com

SAMPLE	Model	Disposable Surgical Face Mask	
	Type	Non-Sterile	
	Color	White	
	Brand	ZEAL	

TEST SERIAL NUMBER	TEST DATE	REPORT DATE
TSN2003018	23.03.2020	24.03.2020

STANDARD	EN 14683+AC:2019 Medical face masks - Requirements and test methods (ASTM F2101-14)

This report is valid only for the samples tested.

IFCGLOBAL Certification Inspection & Training Services GmbH
Hohenzollernring 50, 50672 COLOGNE Tel: 5.1.2e @ifcglobal.de

CERTIFICATE
of Registration

CERTIFIED STAUNCHLY MANAGEMENT SYSTEM

This is to Certify that the

Medical Devices -- Quality Management System

of

MHM KONFEKSİYON GIDA TEMİZLİK MADDELERİ MEDİKAL İNŞAAT MALZEMELERİ SAN. VE TİC. LTD. ŞTİ.

CUMHURİYET MAH. SÜLEYMAN VAHİT CAD. NO:67/ Z01
YÜREĞİR / ADANA / 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:

MANUFACTURE, PURCHASE, SALE, IMPORT AND EXPORT OF MASK (FOR EXAMINATION, POWDER, PARTICULATE POWDER, MOUTH PROTECTOR, DISPOSABLE, HIGH PROTECTION VALVE, LIQUID AND BACTERIA PROOF WASHABLE 5.1.2e TH), CAP, BONE, SHOE COVERS, GLOVES, APRON, SURGICAL FACE MASK, PATIENT AND VISITOR GOWNS, SURGICAL GOWNS, TABLECLOTH, DENTAL UNIT TRAY COVER, STRETCHER COVER, OVERALLS (FOR PATIENTS, DISPOSABLE, SAFE WORKERS), DISPENSARY, STERILE MATERIALS AND DISINFECTANTS

MASKE(MUAYENE, TOZ, PARTÜKÜLLÜ TOZ, AĞIZ KORYUCU, TEK KULLANIMLIK,VENTİLİ YÜKSEK KORUMA, SIVI VE BAKTERİ GEÇİRMEZ YIKANABİLİR AĞIZ İÇİN), KEP,BONE, GALOŞ,ELDİVEN, ÖNLÜK, CERRAHİ YÜZ MASKESİ,HASTA VE ZİYARETÇİ ÖNLÜKLERİ, AMELİYAT ÖNLÜKLERİ,MASA ÖRTÜSÜ,DİŞ ÜNİT TABLA ÖRTÜSÜ,SEDYE ÖRTÜSÜ,TULUM(HASTA, TEK KULLANIMLIK, GÜVENLİ ÇALIŞANLAR İÇİN),DİSPANSER, STERİL MALZEMELERİN VE DEZENFEKTANLARIN İMALATI,ALIMI,SATIMI,İTHALAT VE İHRACATI

:: Certificate No :: TR51746H

Date ofi nitial registration	03 April 2020
Date of this Certificate	03 April 2020
Surveillance audit on or before	02 April 2021
Recertification Due / Certificate expiry	02 April 2023

This Certificate is property of Staunchly Management & System Services Ltd. and remains valid subject to satisfactory surveillance audits.

5.1.2e

IAS ACCREDITED MRCB125

IAF MEMBER OF MUTUAL RECOGNITION ARRANGEMENT

STAUNCHLY MANAGEMENT & SYSTEM SERVICES LTD.
Suite 48, 88-90 Hatton Garden, London, EC1N 8PN.
Phone 5.1.2e
Email : info@staunchlyservices.com Web : www.staunchlyservices.com

SMS/F109A/17/REV02

IFCGLOBAL
Certification Inspection &
Training Services GmbH

Bacterial Filtration Efficiency (BFE)
Differential Pressure (Delta P) Final Report

Summary of performance requirements

Summary (Test Method)

The BFE test is performed to determine the filtration efficiency of test articles by comparing the bacterial control counts upstream of the test article to the bacterial counts downstream. A suspension of Staphylococcus aerosol was aerosolized using a nebulizer and delivered to the test article at a constant flow rate and fixed air pressure. The challenge delivery was maintained at 1.7 - 2.7 x 103 colony forming units (CFU) with a mean particle size (MPS) of 3.0 ± 0.3 pm. The aerosols were drawn through a six-stage, viable particle, Andersen sampler for collection. This test method complies with ASTM F2101-14, EN 14683:2014, Annex B, and AS4381:2015.

The Delta P test is performed to determine the breathability of test articles by measuring the differential air pressure on either side of the test article using a manometer, at a constant flow rate. The Delta P test was designed to comply with MIL-M-36954C, Section 4.4.1.2 and complies with EN 14683:2014, Annex C and AS4381:2015.

All test method acceptance criteria were met. Testing was performed in compliance with US FDA good manufacturing practice (GMP) regulations 21 CFR Parts 210, 211 and 820

Test	Type I[a]	Type II	Type IIR
Bacterial filtration efficiency (BFE), (%)	≥ 95	≥ 98	≥ 98
Differential pressure (Pa/cm2)	<29,4	<29,4	<49,0
Splash resistance pressure (kPa)	Not Required	Not Required	≥ 16,0
Microbial cleanliness (cfu/g)	≤ 30	≤ 30	≤ 30

[a] Type I medical face masks should only be used for patients and other persons to reduce the risk of spread of infections particularly in epidemic or pandemic situations. Type I masks are not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements.

Test Side	:	Inside
BFE Test Area	:	~42 cm^
BFE Flow Rate	:	28.20 Liters per minute (L/min)
Delta P Flow Rate	:	8 L/min
Conditioning Parameters	:	85 ± 5% relative humidity (RH) and 21 ± 5°C for a minimum of 4 hours

This report is valid only for the samples tested.

IFCGLOBAL
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Bacterial Filtration Efficiency (BFE)

Differential Pressure (Delta P) Final Report

Results:			
Test Sample Number	Percent BFE (%)	Delta P (mm Ha_2O/Cm^2)	Delta P(Pa/cm^2)
1	96.3	2.40	25.30
2	96.2	2.50	25.50
3	96.3	2.50	25.20
4	96.2	2.40	25.30
5	96.8	2.60	26.20

The filtration efficiency percentages were calculated using the following equation:
%BFE=(C-T)/C x 100
C: Positive control average,
T: Piece count total recovered downstream of the test article
Note: The Piece count total is available upon request

Mean Positive Control	:	1,945 Colony
Negative Monitor	:	<1 CFU
Mean Particle Size	:	2.9 µm
Test Sample Dimensions	:	~190 mm± X ~ 75mm±
Weight per square metres	:	30x20x30 g/m²

Materials and construction	:	PASS
Design	:	PASS
performance requirements	:	PASS

Test articles with a filtration efficiency greater than or equal to 95% meet the performance requirements of EN 14683 as type I and/or IR
Test articles a differential pressure less than 29.4 Pascals (Pa/cm2) meet the performance requirements of EN 14683 as type I and/or Type II

This report, based on the contract signed between the producer and our body,has been issued on the voluntary field. While displaying the results obtained from the samples submitted to our body by the producer, this report nohow guarantees the production process.

5.1.2e

APPROVED

5.1.2e

This report is valid only for the samples tested.

European Commission
IFCGLOBAL Certification Inspection & Training Services GmbH
Hohenzollernring 50, 50672 COLOGNE 5.1.2e ifcglobal.de