



MASCA DE PROTECTIE N95 / FFP2

Capacitate de filtrare $\geq 95\%$

RESPIRATOR TIP FOLDING
SUDURA ULTRASONICĂ COMPLETĂ

5 STRATURI

PROTECȚIA EXCELENTĂ A PARTICULELOR

STRAT EXTERIOR HIDROFOB

STRATURI INTERIOARE DE FIBRĂ NANO ȘI MELTBLOWN

CAMERA DE RESPIRARE MARE

FĂRĂ LATEX

Despre

IMSAFE Face Mask este eficient din nou cu minimum 95% din particule cu un diametru mediu al masei de 0,3 microni sau mai mare. Măștile purtate corespunzător pot proteja foarte bine împotriva PM10, PM2.5 și a particulelor mai mici.

Masca de protecție IMSAFE asigură respirabilitate, confort și protecție excepționale pentru utilizator.

Materiale

STRATUL DE FATA CU EXTERIOR:
Non-esut filat (hidrofob)

AL DOILEA STRAT:
Topici filtrul suflat

AL treilea strat:
Filtru Nano Fibra Nano

AL patrulea strat:
Non-esut filat

STRAT INTERIOR CU FATA:
Non-esut filat

FIXĂRI:
Capace din spandex din poliuretan tricotat tubular

INTERDICȚII NAZALE:
Aluminiu miez dublu acoperit cu plastic

Caracteristici

- Material de calitate medicală folosit 5
- straturi
- esături cu filtru dublu
- Moale și confortabil
- Bine montat în modelare 3D
- anti-picături
- Inodor
- Fără latex



Standards de calitate

- Fabricat conform unui ISO 9001: 2015, ISO 13485: 2016 într-o instalație fabricat conform
- standardelor europene TS EN 149 + A1: 2009 FFP2 Standarts fabricat conform standardelor
- americane NIOSH-42C FR84

Proprietăți fizice

CULOARE	alb
STIL	Headloop pliat
LUNGIME (± 5mm)	160 mm
LĂȚIME (± 5mm)	105 mm

Sterilizare (dacă este necesar)

Metodă: iradiere gamma

Doza minimă: 25kGy

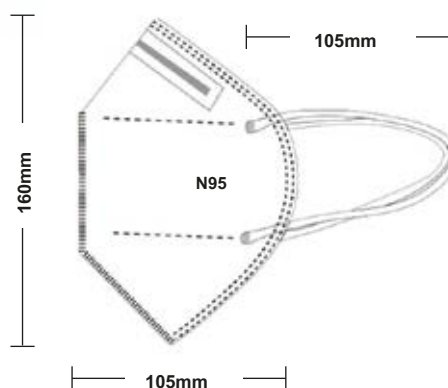
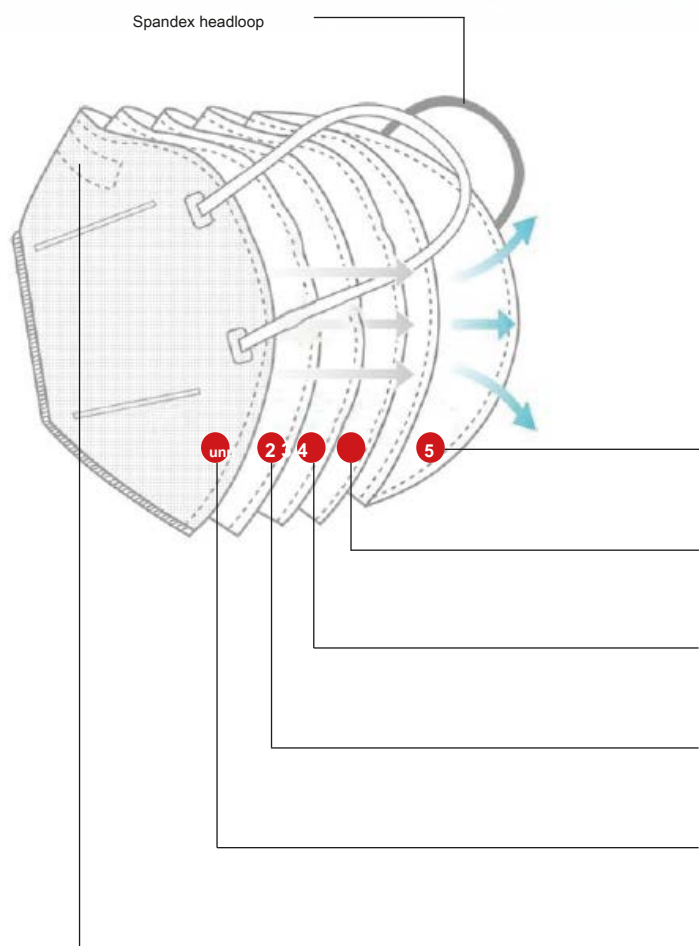
Nivelul de asigurare a sterilității: 10⁻⁶

Perioada de valabilitate și depozitare

- Expiră la 2 ani de la data producției.
- A nu se lăsa la lumina soarelui, la contaminare și la temperaturi ridicate. A se păstra în mediu care nu depășește 80% RH și temperatura de 40 C (104 F).

Informații despre performanță

COMPATIBILITATE	TS EN 149 + A1: 2009 / NIOSH-42C FR84
EFICIENȚA DE FILTRARE A PARTICULELOR (PFE) @ 0,3 MICRON	98,2%
BACTERIAL FILTRATION EFFICIENCY (BFE) @ 3,0 MICRON EFICIENȚA DE	97,9%
FILTRARE VIRALĂ (VFE)	98,5%
PRESIUNEA DIFERENȚIALĂ (ΔP), mmH ₂ O / cm ²	3,57



Al 5-lea strat:

Non-esut filat (30 g / m²)

Al 4-lea strat:

Non-esut filat (25 g / m²)

Al treilea strat:

Filtru non-esut cu fibre nano (60 g / m²)

Al doilea strat:

Filtru topit suflat (25 g / m²)

Primul strat:

Non-esut filat (hidrofob) (50 g / m²)

Bandă din aluminiu cu miez dublu acoperit cu plastic

AB Tip İnceleme Sertifikası EU Type-Examination Certificate

Belge No / Certificate No : 21-20-01-R01
Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /
Certification Date / Certificate Validity Date : 25.01.2021-29.07.2025
Belge Geçerlilik Tarihi / Document Validity Period : 5 yıl / 5 years
Firma Unvanı ve Adresi /
Company Name and Address : MOGEYL BOR SAVUNMA UZAY
TEKNOLOJİLERİ SAN. TİC. A.Ş.
Alcı OSB Mah. 2014. Cad. No:14 Sincan
/ANKARA

Ürün Adı /Modeller / Product Name / Models : IMSAFE K-10 FFP2 NR
Direktifi / Directive : 2016/425 REGULATION
Modülü/Kategori / Module / Category : B MODÜLÜ/ KATEGORİ III
MODULE B / CATEGORY III
Test Rapor No/ları / Test Report No : MNA M-2020-00202

Ürün Tipi / Product Type:

- EN 149:2001+ A1:2009 Solunumla ilgili koruyucu cihazlar - Parçacıklara karşı koruma amaçlı filtreli yarım maskeler/ Respiratory protective devices - Filtering half masks to protect against particles

Ürünün Malzeme Bilgisi / Product Material Information: IMSAFE K-10 FFP2 NR model ürünleri kumaş, kulak kayışı, burun klipsi ve filtre katmanı kullanılarak imal edilmiştir./ IMSAFE K-10 FFP2 NR model products are manufactured using fabric, ear strap, nose clip, filter layer.

Revizyon nedeni/ Reason for revision: Standart yayın tarihi ve resim revize edilmiştir./ The current date of the product standard and the product image have been revised.

Volkan AKIN
25.01.2021
Karar Verici / Approver

Okan AKEL
25.01.2021
Şirket Müdürü / General manager



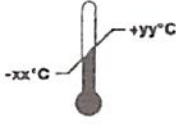
ATTACHMENTS (21-20-01-R01)

To certify the PPE product at Category III level, C2 or D module is accompanied by applying one of the conformity assessment methods along with the EU Type Examination (Module B).

Model : IMSAFE K-10 FFP2 NR

PPE SPECIFICATION	PERFORMANCE LEVELS
Classification	FFP2
Reusable / Single Shift Use	NR

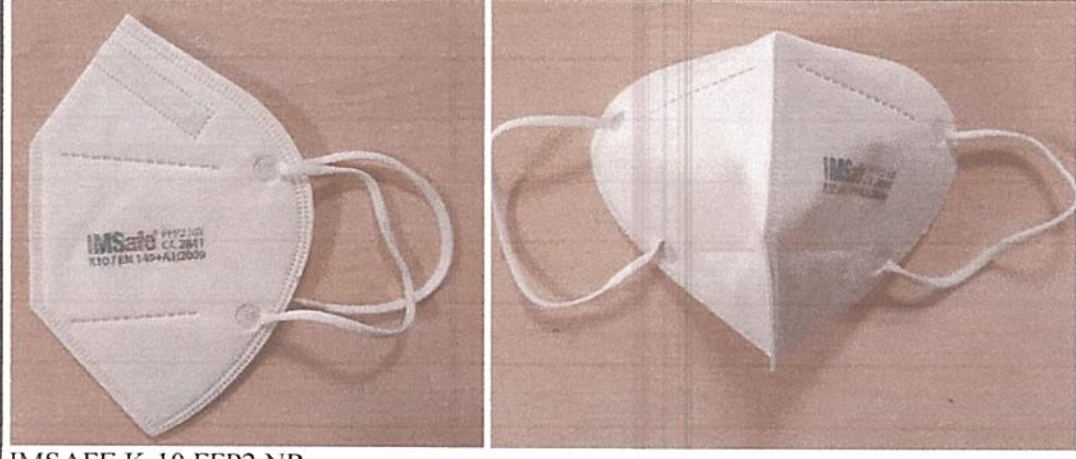
PPE produced as a single unit to fit an individual user, all the necessary instructions for manufacturing such PPE on the basis of the approved basic model:

MARKING	
MANUFACTURER: MOGEYL BOR SAVUNMA UZAY TEKNOLOJİLERİ SAN. TİC. A.Ş.	
PPE TYPE :	
- EN 149:2001+ A1:2009 Respiratory protective devices - Filtering half masks to protect against particles	
MODEL: IMSAFE K-10 FFP2 NR	
PICTOGRAM AND PERFORMANCE LEVELS:	
EN 149:2001+ A1:2009 FFP2 NR	
 NB 2841	
 Year Month	 yyyy/mm
 -xx°C +yy°C	 < xx%
Or Condition of Storage	

MNA LABORATORIES SAN. TIC. LTD. ŞTİ declares that the above-mentioned product meets the requirements of the directive according to the EU Directive 2016/425, the safety of the product is covered by the conditions and use specified in this certificate and in the technical file.

ATTACHMENTS (21-20-01-R01)

PRODUCT PICTURES



IMSAFE K-10 FFP2 NR

DOCUMENTS IN THE TECHNICAL FILE

- Basic Health Safety Requirements
- Risk Assessment
- Test Reports
- Technical Report

MNA Laboratuvarları San. Tic.Ltd .Şti

Adres: Küçükbakkalköy Mahallesi Yenidoğan Cad.No:21 Ataşehir/ İstanbul

Tel: 0216 574 07 08 Faks: 0216 575 13 31 www.mnalab.com

U-Form-002/Rev.04/12.03.2020

 MNA LABORATUVARLARI SAN. TİC. LTD. ŞTİ.	MNA LABORATUVARLARI
	TECHNICAL EVALUATION REPORT(21-20-01-R01)

Report No : 21-20-01-R01

Report Date : 25.01.2021

Application No : 21-20-01-R01

1. COMPANY INFORMATION:

MOGEYL BOR SAVUNMA UZAY TEKNOLOJİLERİ SAN. TİC. A.Ş.

Alcı OSB Mah. 2014. Cad. No:14 Sincan /ANKARA

Tel: + 90 312 511 16 16

E-mail: sozturk@mogeyl.com.tr

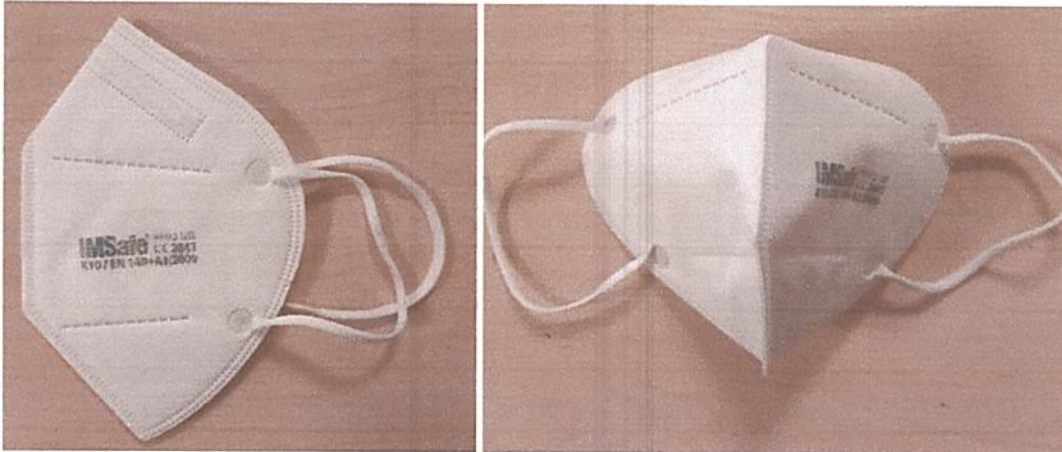
2. PPE INFORMATION:

Disposable, non-sterile, half mask made of particulate protection filter material.

3. PPE TYPE IDENTIFICATION

EN 149:2001+A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking

4. PPE PICTURES



IMSAFE K-10 FFP2 NR

5. PPE DIMENSIONS:

IMSAFE K-10 FFP2 NR model has been found to be produced using standard sizes.

6. PPE PRODUCT MATERIAL INFORMATION:

The mask is made of cotton elastic ear strap, non-woven fabric on the outer and inner layers and filter material on the middle layer.

7. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS

- A visual inspection was made according to EN 149:2001+A1:2009 for ergonomics.
- Protection levels and degrees are defined by the manufacturer.
- Suitable construction materials were determined by visual inspection according to EN 149:2001+A1:2009.
- Respiratory protective dimensions are evaluated according to EN 149:2001+A1:2009.
- Conditioning EN 149:2001+A1:2009 part 8.3, Penetration EN 149:2001+A1:2009 part 8.11 (EN 13274-7), Application performance EN 149:2001+A1:2009 part 8.4, Inward leakage EN 149:2001+A1:2009 part 8.5, Flammability EN 149:2001+A1:2009 part 8.6, The carbon dioxide content of the inhaled air EN 149:2001+A1:2009 part 8.7, Inhalation resistance EN 149:2001+A1:2009 part 8.9, Exhalation resistance EN 149:2001+A1:2009 part 8.9 has been tested and evaluated.

8. ANALYSIS AND EVALUATIONS:

EN 149:2001+A1:2009

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Visual inspection	Shall also the marking and the information supplied by the manufacturer				Appropriate	-	PASS
Total inward leakage	At least 46 out of the 50 individual exercise result	<25	<11	<5	9,6	FFP2	PASS
	At least 8 out of the 10 individual wearer	<22	<8	<2	7,4	FFP2	PASS
Flammability	Mask shall not burn or not to continue to burn for more than 5 s				Flame not seen	-	PASS
Carbondioxide content of the inhalation air	Shall not exceed an average of % 1				0,9	-	PASS
Penetration of filter material	Sodium chloride, 95 L/min %, max	% 20	% 6	% 1	3,0	FFP2	PASS
	Paraffin oil, 95 L/min %, max	% 20	% 6	% 1	5,2	FFP2	PASS
Compatibility with skin	Materials shall not be known to be likely to cause irritation or any other adverse effect				Appropriate	-	PASS

	to health						
Head harness	It can be donned and removed easily				Appropriate	-	PASS
Breathing Resistance	Inhalation 30L/min	0,6 mbar	0,7 mbar	1 mbar	0,3	FFP2	PASS
	Inhalation 95L/min	2,1 mbar	2,4 mbar	3 mbar	1,6	FFP2	PASS
	Exhalation 160L/min	3 mbar	3 mbar	3 mbar	1,9	FFP2	PASS

9. DECISION PROPOSAL

Analysis and examinations in IMSAFE K-10 FFP2 NR model coded personal respiratory protection; Respiratory Protective Devices EN 149:2001+A1:2009- Filtered Half Masks for Protection Against Particles - Properties, Experiments and Marking standards are evaluated. It is recommended to document it at the specified performance levels as a result of the technical evaluations.

10. ATTACHMENTS

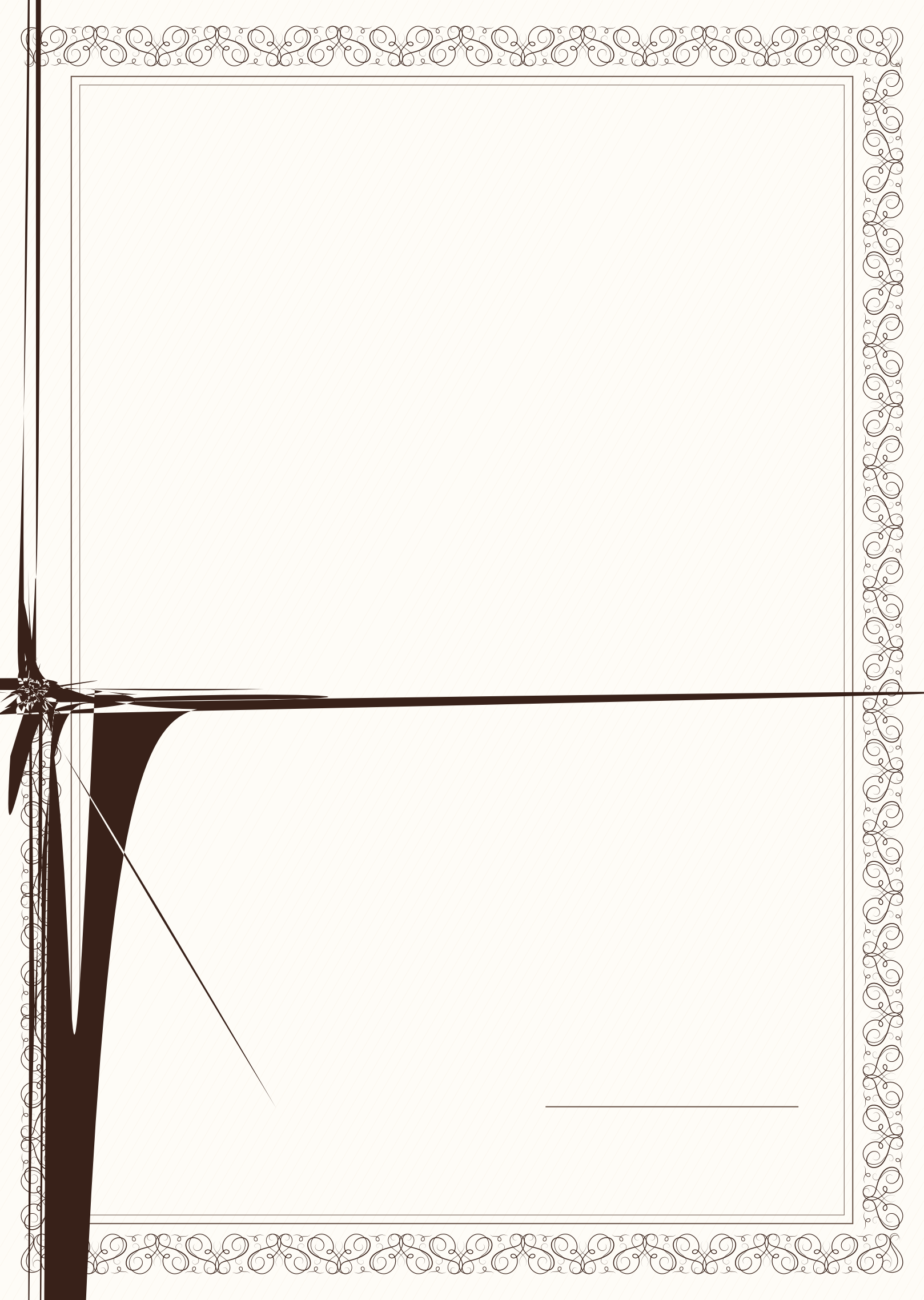
- Basic Health Safety Requirements
- Risk Assessment
- Test Reports
- User Instruction

Reason for revision : The current date of the product standard and the product image have been revised.

CONTROLLER : VOLKAN AKIN

SING :

DATE : 25.01.2021





SYNDICATE OF INTERNATIONAL SYSTEM CERTIFICATIONS



SYNDICATE OF INTERNATIONAL SYSTEM

Managing Director



CERTIFICATE of Registration



Aceasta este pentru a certifica că

Dispozitive medicale - Sistem de management al calității

Ugh

**MOGEYL BOR DEFENSE SPACE TECHNOLOGIES
SANAYİ TİCARET ANONİM ŞİRKETİ**

ALCI OSB MAH. 2014 CAD. NU: 14 SİNCAN / Ankara / TURCIA

**a fost evaluat independent și este conform
cu cerințele**

ISO 13485: 2016

Acest certificat se aplică următoarelor game de produse sau servicii:

PRODUCȚIE ȘI VÂNZĂRI DE MASCĂ CHIRURGICALĂ ȘI MASCĂ DE PROTECȚIE

MASCĂ CHIRURGICALĂ ȘI PRODUCȚIA ȘI VÂNZAREA MASCILOR DE PROTECȚIE

:: Certificat nr. : TR52366H

Data înregistrării inițiale Data	16 mai 2020
acestui certificat	16 mai 2020
Audit de supraveghere la sau înainte	15 mai 2021
Recertificare scadentă / expirarea certificatului	15 mai 2023

Acest certificat este proprietatea Staunchly Management & System Services Ltd. și rămâne valabil
supuse unor audituri de supraveghere satisfăcătoare.

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

SMS/F109A/17/REV02

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 demanded