

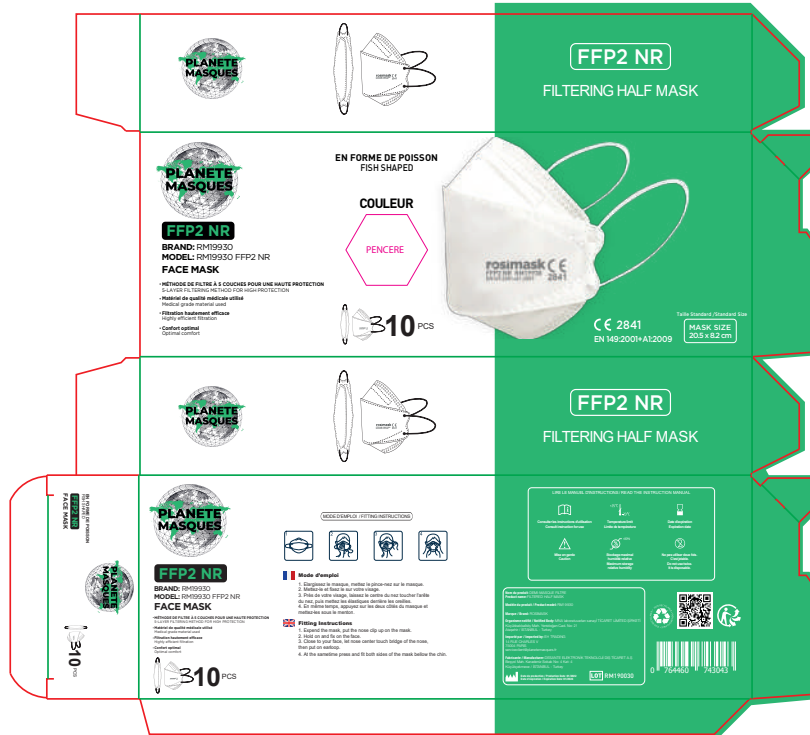
MASQUE FFP2

MARQUE PLANETE MASQUES

NORME EN149:2001+A1:2009

CERTIFIÉ CE

COULEUR BLANC



DESCRIPTIF

- **Masque médical non tissé (60%) et tissu fondu (40%)**
- **5 couches de protection**
- **Fixation par boucles élastiquées**
- **Efficacité de filtration bactérienne >95 %**
- **Couleur BLANC**
-

Conditionnement

- . Carton de 1 000 masques
- . 100 boites de 10 masques (10 sachets de 1 masque)
- . Poids par carton 9 kg
- . Dimension :
 - Hauteur : 460 mm
 - Largeur : 410 mm
 - Longueur : 500 mm

**Palette de 16 cartons (16 000 masques)
hauteur 192 cm**

**Palette de 20 cartons (20 000 masques)
Hauteur 242 cm**

Code EAN : 0764460743043

Certificat de conformité



EU-Konformitätserklärung

EU-Declaration of Conformity

Dokument-Nr. / Document No. 202008

Wir / we :Desante Elektronik Teknoloji Dış Ticaret A.Ş
Beşyol Mah. Karadeniz Sk. No:4 Kat:4 Küçükçekmece/İstanbul/ Türkiye

erklären in alleiniger Verantwortung, dass das Produkt
declare under our sole responsibility that the product

Partikelfiltrierende Halbmaske
Name/Typ: RM-19930 , Marke/Brand:ROSIMASK
(Größen: Standardgröße) (Sizes: Standard size)
Particle filtering half mask
Classification FFP2 NR

mit der EU-Baumusterprüfbescheinigung

is in conformity with the EU-Type Examination Certificate M-2021-00035

ausgestellt von der notifizierten Stelle mit
der Kenn-Nr.
issued by the Notified Body with Identification
No: 2841

Name und Anschrift der notifizierten Stelle
MNA Laboratuvarları san. Tic. Ltd. Şti.
Küçükbakkalköy Mahallesi Yenidoğan Caddesi No.21
Ataşehir/İst/Türkiye

und mit der folgenden Harmonisierungsrechtsvorschrift der Union unter Anwendung der
aufgeführten Norm übereinstimmt:
and is in compliance with the following Union harmonisation legislation by application of the listed
standard

Bestimmungen der Verordnung provisions of regulation	Nummer sowie Ausgabedatum der Norm Number and date of issue of standard
Verordnung (EU) 2016/425	EN 149:2001+A1:2009
Verordnung über persönliche Schutz-ausrüstungen Personal Protective Equipment Regulation	

- o oder: Überwachung der Konformität mit der Bauart auf der Grundlage einer internen Fertigungskontrolle mit überwachten Produktprüfungen in unregelmäßigen Abständen (Modul C2) durch:
Surveillance of conformity to type based on internal production control plus supervised product checks at random intervals (Module C2)
by:MNA Laboratuvarları san. Tic. Ltd. Şti.
Küçükbakkalköy Mahallesi Yenidoğan Caddesi No.21 Ataşehir/İst/Türkiye
Zertifikat-Nr. 147-21-03
Certificate No.

İstanbul/24.08.2021

Ort und Datum
Place and date

Cevdet Darendé
General Manager

Name/Funktion
Name/Function

DESANTE ELEKTRONİK
TEKNOLOJİ DİŐ TİCARET A.Ő.
Beşyol Mah. Karadeniz Sok. No:4 Kat :4
Küçükçekmece-İSTANBUL
Küçükçekmece V.D. : 249 065 20 00
Tic. Sic. No: 249065-5

Certificat ISO 9001 : 2015 Usine



CERTIFICATE

DESANTE ELEKTRONİK TEKNOLOJİ DİŞ TİCARET ANONİM ŞİRKETİ
BEŞYOL MAH. KARADENİZ SK. NO:4 İÇ KAPI NO:4 KÜÇÜKÇEKMECE /İSTANBUL

KAPSAM: İŞINLAMA ELEKTROMEDİKAL VE ELEKTROTHERAPİ İLE İLGİLİ CİHAZLARIN İMALATI
(ELEKTRO -KARDİYOĞRAFI CİHAZI, İŞİTME CİHAZI, RADYOLOJİ CİHAZ, RÖNTGEN CİHAZLARI, X, ALFA, BETA, GAMA, MOR ÖTESİ VE KIZIL ÖTESİ İŞINLARIN KULLANIMINA DAYALI CİHAZLAR, VB.)
SOLUNUMLA İLGİLİ KORUYUCU CİHAZLAR PARÇACIKLARA KARŞI KORUMA AMAÇLI FİLTRELİ YARIM MASKE (Ffp2-Ffp3 MASKE)

SCOPE: MANUFACTURING OF IRRADIATION ELECTROMEDICAL AND ELECTROTHERAPY-RELATED DEVICES (ELECTRO-CARDIOGRAPHY DEVICE, HEARING AID, RADIOLOGY DEVICE, X-RAY DEVICES, X, ALFA, BETA, GAMA DEVICES, DEVICES, DEVICES, etc.)
RESPIRATORY PROTECTIVE DEVICES FILTERED HALF MASK FOR PROTECTION AGAINST PARTICLES (Ffp2-Ffp3 MASK)

TS EN ISO 9001:2015 KALİTE YÖNETİM SİSTEMİ (QUALITY MANAGEMENT SYSTEM)

Kurduğumu ve uyguladığımı belgelemekte ve EKOL tarafından gerçekleştirilen denetim bu yönetim sisteminin yukarıda belirtilen standardın şartlarını karşıladığını doğrulamaktadır.

It certifies that it is established and implemented, and the audit performed by EKOL it confirms that this management system meets the requirements of the following standard.

Sertifika Numarası / Certificate Number	: 9101925232
Sertifika Kodu / Certificate Code	: DESANTE
Sertifika Yayın Tarihi / Certificate Issue Date	: 23.09.2021
Sertifika Geçerlilik Tarihi / Certificate Validity Date	: 23.09.2022
Sertifika Periyodu / Certificate Period	: 1 Yıl / 1 Year



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sorumluluk göstermesine rağmen büyük ihmallerde dahil sorumluluk kabul etmeyecektir.
Belgenin mülkiyet hakkı EKOL aittir ve istenilince iade edilecektir.
www.ekolbelgelendirme.com info@ekolbelgelendirme.com



Ekol Belgelendirme Şirketi

Maslak Mah. Maslak Meydan Sokak. Beybi Giz Plaza No:1 Kat:15 D:55
Sarıyer / İstanbul / Türkiye Tel: +90 212 909 12 07 www.ekolbelgelendirme.com
Belgenin geçerlilik durumu <https://www.ekolbelgelendirme.com/sertifika/su/> adresinden kontrol edilebilir.

Certificat ISO 14001 : 2015 Usine



CERTIFICATE

DESANTE ELEKTRONİK TEKNOLOJİ DIŞ TİCARET ANONİM ŞİRKETİ
BEŞYOL MAH. KARADENİZ SK. NO:4 İÇ KAPI NO:4 KÜÇÜKÇEKMECE /İSTANBUL

KAPSAM: İŞİNLAMA ELEKTROMEDİKAL VE ELEKTROTHERAPİ İLE İLGİLİ CİHAZLARIN İMALATI (ELEKTRO -KARDİYOĞRAFI CİHAZI, İŞİTME CİHAZI, RADYOLOJİ CİHAZ, RÖNTGEN CİHAZLARI, X, ALFA, BETA, GAMA, MOR ÖTESİ VE KIZIL ÖTESİ İŞINLARIN KULLANIMINA DAYALI CİHAZLAR, VB.) SOLUNUMLA İLGİLİ KORUYUCU CİHAZLAR PARÇACIKLARA KARŞI KORUMA AMAÇLI FİLTRELİ YARIM MASKE (Ffp2-Ffp3 MASKE)

SCOPE: MANUFACTURING OF IRRADIATION ELECTROMEDICAL AND ELECTROTHERAPY-RELATED DEVICES (ELECTRO-CARDIOGRAPHY DEVICE, HEARING AID, RADIOLOGY DEVICE, X-RAY DEVICES, X, ALFA, BETA, GAMA DEVICES, DEVICES, DEVICES, DEVICES, etc.) RESPIRATORY PROTECTIVE DEVICES FILTERED HALF MASK FOR PROTECTION AGAINST PARTICLES (Ffp2-Ffp3 MASK)

ISO 14001:2015 ÇEVRE YÖNETİM SİSTEMİ (ENVIRONMENTAL MANAGEMENT SYSTEM)

Kurduğunu ve uyguladığını belgelemekte ve EKOL tarafından gerçekleştirilen denetim bu yönetim sisteminin yukarıda belirtilen standardın şartlarını karşıladığını doğrulamaktadır.

It certifies that it is established and implemented, and the audit performed by EKOL it confirms that this management system meets the requirements of the following standard.

Sertifika Numarası / Certificate Number	: 9101925383
Sertifika Kodu / Certificate Code	: DESANTE
Sertifika Yayın Tarihi / Certificate Issue Date	: 26.12.2021
Sertifika Geçerlilik Tarihi / Certificate Validity Date	: 26.12.2022
Sertifika Periyodu / Certificate Period	: 1 Yıl / 1 Year



Ekol Belgeleme Şirketi

Maslak Mah. Maslak Meydan Sokak. Beybi Giz Plaza No:1 Kat:15 D:55
Sarıyer / İstanbul / Türkiye **Tel:** +90 212 909 12 07 www.ekolbelgeleme.com

Belgenin geçerlilik durumu <https://www.ekolbelgeleme.com/sertifikaara/> adresinden kontrol edilebilir.

Rapport de Test : Module B



AB Tip İnceleme Sertifikası EU Type-Examination Certificate

Belge No / Certificate No : 147-21-02-R01
Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /
Certification Date / Certificate Validity Date : 23.08.2021-04.02.2026
Belge Geçerlilik Tarihi / Document Validity Period: 5 yıl / 5 years
Firma Unvanı ve Adresi /
Company Name and Address : DESANTE ELEKTRONİK TEKNOLOJİ DİŞ
TİC. A.Ş.
Beşyol Mah. Karadeniz Sk. Polaris Tekstil Blok
No: 4 İçk: 4 Küçükçekmece / İSTANBUL

Ürün Adı /Modeller / Product Name / Models : ROSİMASK RM19930
Direktifi / Directive : 2016/425 REGULATION
Modülü/Kategori / Module / Category : B MODÜLÜ/ KATEGORİ III
MODULE B / CATEGORY III
Test Rapor No'ları / Test Report No : M-2021-00035

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

Ürünün Malzeme Bilgisi / Product Material Information: ROSİMASK RM19930 model ürünleri kumaş,
elastik kayış, burun klipsi ve filtre katmanı kullanılarak imal edilmiştir./ ROSİMASK RM19930 model
products are manufactured using fabric, elastic strap, nose clip, filter layer.

Revizyon nedeni / Reason for revision: Firma bilgileri revize edilmiştir./ Company information has been
revised.

Volkan AKIN
23.08.2021
Karar Verici / Approver

Okan AKEL
23.08.2021
Şirket Müdürü / General manager



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



Notified Body Number: 2841




ATTACHMENTS (147-21-02-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 : ROSIMASK RM19930

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: DESANTE ELEKTRONİK TEKNOLOJİ DIŞ TIC. A.Ş.					
PPE TYPE:					
- EN 149:2001+ A1:2009 Respiratory protective devices - Filtering half masks to protect against particles					
MODEL: ROSIMASK RM19930					
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.

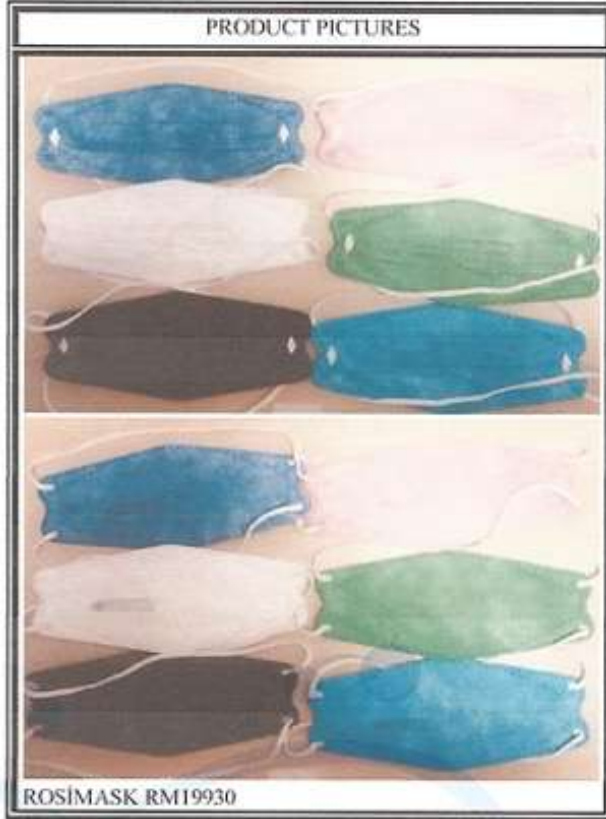
MNA Laboratuvarları San. Tic.Ltd. Şti
Adres: Küçükbakkalköy Mahallesi Yenidoğan Cad.No:21 Ataşehir/ İstanbul
Tel: 0216 574 07 08 Faks: 0216 575 13 31 www.mnalab.com

U-Form-002/Rev.04/12.03.2020



Notified Body Number: 2841


ATTACHMENTS (147-21-02-R01)



DOCUMENTS IN THE TECHNICAL FILE
<ul style="list-style-type: none">- 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-Ferm-002/Rev.04/12.03.2020

 MNA LABORATUVARLARI SAN. TIC. LTD. ŞTİ	MNA LABORATUVARLARI
	TECHNICAL EVALUATION REPORT (147-21-02-R01)

Report No :147-21-02-R01

Report Date :23.08.2021

Application No :147-21-02-R01

1. COMPANY INFORMATION:

DESANTE ELEKTRONİK TEKNOLOJİ DİŞ TİC. A.Ş.

Beşyol Mah. Karadeniz Sk. Polaris Tekstil Blok No: 4 İçk: 4 Küçükçekmece / İSTANBUL

2. PPE INFORMATION:

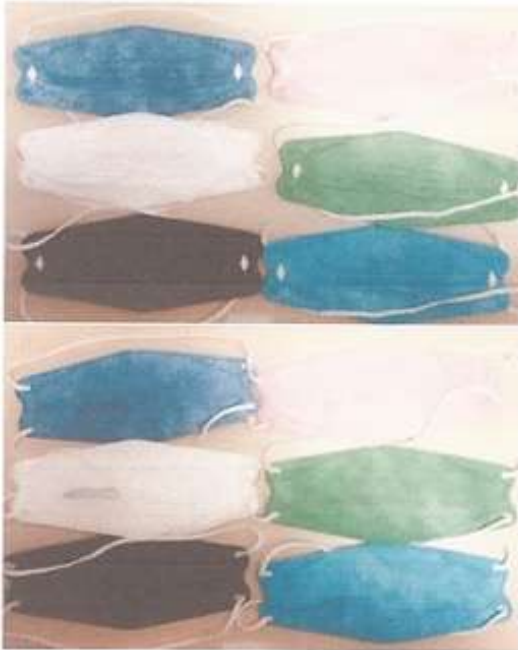
Disposable and non-sterile half mask made of particulate protection filter material.

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




5. PPE DIMENSIONS:

ROSİMASK RM19930 model has been found to be produced using standard sizes.

6. PPE PRODUCT MATERIAL INFORMATION:

The product is made of elastic strap, nonwoven fabric on the outer and inner layers and filter material on the middle layer.

 <small>MNA LABORATUVARLARI SAN. TIC. LTD. ŞTİ.</small>	MNA LABORATUVARLARI
	TECHNICAL EVALUATION REPORT (147-21-02-R01)

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
Banned Azo Dyes	≤30 mg/kg				≤ 5 mg/kg	≤ 30 mg/kg	PASS
Total inward leakage	At least 46 out of the 50 individual exercise result	<25	<11	<5	See the table below	FFP2	PASS
	At least 8 out of the 10 individual wearer arithmetic means	<22	<8	<2	See the table below	FFP2	PASS


Total Inward Leakage (%)						
	Exercise 1	Exercise 2	Exercise 3	Exercise 4	Exercise 5	Average
Subject 1 (As recieved)	6.5	5.9	7.4	7.6	7.7	7.0
Subject 2 (As recieved)	6.7	5.9	4.7	7.8	7.6	6.5
Subject 3 (As recieved)	6.8	5.8	7.4	7.0	7.4	6.9
Subject 4 (As recieved)	6.5	8.0	7.3	8.7	7.6	7.6
Subject 5 (As recieved)	6.2	8.2	8.0	3.6	7.6	6.7
Subject 6 (After temperature conditioning)	6.1	6.8	6.6	6.1	7.6	6.6
Subject 7 (After temperature conditioning)	5.9	7.1	6.5	7.4	6.0	6.6
Subject 8 (After temperature conditioning)	6.2	6.5	6.2	7.6	7.5	6.8
Subject 9 (After temperature conditioning)	6.2	6.4	6.1	7.4	6.0	6.4
Subject 10 (After temperature conditioning)	6.3	7.4	7.6	7.4	6.2	7.0

 MNA LABORATUVARLARI SAN. TIC. LTD. ŞTİ.	MNA LABORATUVARLARI	
	TECHNICAL EVALUATION REPORT (147-21-02-R01)	

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Flammibility	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				0,72 0,79 0,71	-	PASS
Penetration of filter material	Sodium chloride, 95 L/min % , max	% 20	% 6	% 1	See the table below	FFP2	PASS
	Paraffin oil, 95 L/min % , max	% 20	% 6	% 1	See the table below	FFP2	PASS

Penetration of filter material	Sodium Chloride (%)	Paraffin Oil (%)
As recieved	3.7	4.0
As recieved	3.3	4.5
As recieved	4.1	4.1
After the simulated wearing treatment	3.2	3.8
After the simulated wearing treatment	3.3	4.2
After the simulated wearing treatment	3.0	4.6
Mechanical strength and temperature conditioning	4.9	5.5
Mechanical strength and temperature conditioning	5.1	5.1
Mechanical strength and temperature conditioning	5.3	5.4

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Compatibility with skin	Materials shall not be known to be likely to cause irritation or any other adverse effect to health				Appropriate	-	PASS
Head harness	It can be donned and removed easily				Appropriate	-	PASS
Breathing Resistance	Inhalation 30L/min	0,6 mbar	0,7 mbar	1 mbar	See the table below	FFP2	PASS
	Inhalation 95L/min	2,1 mbar	2,4 mbar	3 mbar	See the table below	FFP2	PASS
	Exhalation 160L/min	3 mbar	3 mbar	3 mbar	See the table below	FFP2	PASS

 MNA LABORATUVARLARI SAN. TIC. LTD. STI	MNA LABORATUVARLARI
	TECHNICAL EVALUATION REPORT (147-21-02-R01)

Breathing Resistance (mbar)	Inhalation 30L/min	Inhalation 95L/min
As recieved	0.3	2.0
As recieved	0.3	2.0
As recieved	0.3	2.1
After temperature conditioning	0.4	2.1
After temperature conditioning	0.3	2.1
After temperature conditioning	0.4	2.0
After the simulated wearing treatment	0.4	2.1
After the simulated wearing treatment	0.3	2.0
After the simulated wearing treatment	0.4	2.1

Breathing Resistance 160L/min (mbar)	Facing directly ahead	Facing vertically upwards	Facing vertically downwards	Lying on the left side	Lying on the right side
As recieved	2.1	2.2	2.1	2.1	2.2
As recieved	2.2	2.1	2.2	2.2	2.1
As recieved	2.1	2.1	2.1	2.2	2.2
After temperature conditioning	2.2	2.2	2.2	2.1	2.2
After temperature conditioning	2.1	2.2	2.1	2.2	2.2
After temperature conditioning	2.2	2.1	2.2	2.1	2.2
After the simulated wearing treatment	2.1	2.2	2.1	2.2	2.1
After the simulated wearing treatment	2.2	2.1	2.2	2.1	2.2
After the simulated wearing treatment	2.2	2.2	2.2	2.2	2.2

9. DECISION PROPOSAL

Analysis and examinations ROSIMASK RM19930 model coded personal protective equipment; 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 be certified at the performance levels specified as a result of technical evaluations.

10. ATTACHMENTS

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

Reason for revision : Company information has been revised.

CONTROLLER : VOLKAN AKIN

SIGNATURE :

DATE : 23.08.2021



Rapport de Test : Module C2



CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTION CONTROL PLUS SUPERVISED
PRODUCT CHECKS AT RANDOM INTERVALS (MODULE C2)

MODÜL C2 - ÜRETİMİN DÂHİLİ KONTROLÜ VE ÜRÜNÜN RASTGELE
ARALIKLARLA DENETİMLİ MUAYENESİNE DAYALI TİPE UYGUNLUK

Belge No / Certificate No : 147-21-02-01-R01
Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /
Certification Date / Certificate Validity Date : 23.08.2021-12.07.2022
Belge Geçerlilik Tarihi / Document Validity Period: 1 yıl / 1 year
Firma Unvanı ve Adresi /
Company Name and Address : DESANTE ELEKTRONİK TEKNOLOJİ DİŞ
TİC. A.Ş.
Beşyol Mah. Karadeniz Sk. Polaris Tekstil Blok No:
4 İçk: 4 Küçükçekmece / İSTANBUL
Ürün Adı /Modeller / Product Name / Models : ROSIMASK RM19930
Direktifi / Directive : 2016/425 REGULATION
Modüllü/Kategori / Module / Category : C2 MODÜLÜ/ KATEGORİ III
MODULE C2 / CATEGORY III
Test Rapor No'ları / Test Report No : M-2021-00553
Ürün Tipi / Product Type:

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

Ürünün Malzeme Bilgisi / Product Material Information: ROSIMASK RM19930 model ürünleri kumaş,
elastik kayış, burun klipsi, filtre katmanı kullanılarak imal edilmiştir./ ROSIMASK RM19930 model products
are manufactured using fabric, elastic strap, nose clip, filter layer.

Revizyon nedeni / Reason for revision: Firma bilgileri revize edilmiştir./ Company information has been
revised.

Erhan ÜSTÜNEL
23.08.2021
Karar Verici / Approver

Okan AKEL
23.08.2021
Şirket Müdürü / General manager



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-FRM-056.REV.00.YAYIN TARİHİ:20.11.2019



mna

Notified Body Number: 2841

**CONFORMITY TO TYPE BASED ON INTERNAL
PRODUCTION CONTROL PLUS SUPERVISED PRODUCT
CHECK AT RANDOM INTERVALS
(MODULE C2, ANNEX VII) (147-21-02-01-R01)**

Report No : 147-21-02-01-R01

Report Date : 23.08.2021

Application No : 147-21-02-01-R01

1. COMPANY INFORMATION:

DESANTE ELEKTRONİK TEKNOLOJİ DİŞ TİC. A.Ş.

Beşyol Mah. Karadeniz Sk. Polaris Tekstil Blok No: 4 İçk: 4 Küçükçekmece / İSTANBUL

2. PPE INFORMATION:

Disposable and 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



ROSİMASK RM19930

5. PPE DIMENSIONS:

ROSİMASK RM19930 model has been found to be produced using standard sizes.

6. PPE PRODUCT MATERIAL INFORMATION:

The mask is made of elastic strap, nonwoven fabric on the outer and inner layers and filter material on the middle layer.



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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.

**8. ANALYSIS AND EVALUATIONS:
EN 149:2001 +A1:2009**

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Part 7.3 Visual inspection	Shall also the marking and the information supplied by the manufacturer				Appropriate	-	PASS
Banned Dyes	Azo	< 30 mg/kg			< 5 mg/kg	-	PASS
Part 7.4 Packaging	Particle filtering half mask shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.				Appropriate	-	PASS
Part 7.5 Material	When conditioned in accordance 8.3.1 & 8.3.2 the particle filter half mask shall not collapse.				Appropriate	-	PASS
Part 7.6 Cleaning and disinfecting	After cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant class.				Not applicable	-	Not applicable
Part 7.7 Practical performance	No negative comments should be made by the test subject regarding any of the criteria evaluated.				Appropriate	-	PASS
Part 7.8 Finish of parts	Parts of the device likely to come into contact with the wearer shall have no sharp edge or burrs.				Appropriate	-	PASS

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Part 7.9.1 Total inward leakage	At least 46 out of the 50 individual exercise result	<25	<11	<5	See the table below	FFP2	PASS
	At least 8 out of the 10 individual wearer arithmetic means	<22	<8	<2	See the table below	FFP2	PASS

Total Inward Leakage (%)

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	Exercise 1	Exercise 2	Exercise 3	Exercise 4	Exercise 5	Average
Subject 1 (As received)	7,0	6,0	6,0	7,2	5,5	6,3
Subject 2 (As received)	6,7	6,0	7,2	5,5	5,4	6,2
Subject 3 (As received)	6,4	6,5	4,9	7,2	7,6	6,5
Subject 4 (As received)	7,8	7,2	6,9	7,3	7,6	7,4
Subject 5 (As received)	6,1	7,3	6,7	4,4	6,2	6,1
Subject 6 (After temperature conditioning)	6,6	6,5	6,6	6,7	7,7	6,8
Subject 7 (After temperature conditioning)	6,4	6,6	6,3	5,3	6,2	6,2
Subject 8 (After temperature conditioning)	7,7	6,7	7,6	7,8	6,2	7,2
Subject 9 (After temperature conditioning)	6,0	6,5	7,6	7,2	6,5	6,8
Subject 10 (After temperature conditioning)	6,1	6,5	6,6	6,8	6,9	6,6

Subject facial dimensions

Subject	Face Length (mm)	Face Width (mm)	Face Depth (mm)	Mouth Width (mm)
1	133	132	132	65
2	125	144	116	67
3	126	135	124	75
4	123	133	134	74
5	117	135	122	73
6	122	142	133	66
7	113	132	114	75
8	135	123	123	65
9	122	135	133	74
10	135	142	125	83

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Part 7.9.2 Penetration of filter material	Sodium chloride, 95 L/min % max	% 20	% 6	% 1	See the table below	FFP2	PASS
	Paraffin oil, 95 L/min % max	% 20	% 6	% 1	See the table below	FFP2	PASS

Penetration of filter material	Sodium Chloride (%)	Paraffin Oil (%)
As received	4,4	4,4
As received	4,6	4,4
As received	4,4	4,8
After the simulated wearing treatment	4,3	5,0
After the simulated wearing treatment	4,7	4,7
After the simulated wearing treatment	4,6	5,1
Mechanical strength and temperature conditioning (120 mg)	5,6	5,7
Mechanical strength and temperature conditioning (120 mg)	5,8	5,9
Mechanical strength and temperature conditioning (120 mg)	5,6	5,8

TESTS	PARAMETER	PERFORMANCE	RESULTS	PERFORMANCE	EVALUATION
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		LEVELS				LEVELS	
		FFP1	FFP2	FFP3			
Part 7.10 Compatibility with skin	Materials shall not be known to be likely to cause irritation or any other adverse effect to health.	Appropriate			-		PASS
Part 7.11 Flammibility	Mask shall not burn or not to continue to burn for more than 5 s	Flame not seen			-		PASS
Part 7.12 Carbondioxide content of the inhalation air	Shall not exceed an average of % 1	0,66 0,77 0,75			-		PASS
Part 7.13 Head harness	It can be donned and removed easily	Appropriate			-		PASS
Part 7.14 Field of vision	The field of vision shall acceptable in practical performance test.	Appropriate			-		PASS
Part 7.15 Exhalation valve(s)	It shall withstand axially a tensile force of 10 N apply for 10 s. If fitted, shall continue to operate correctly after a continuous exhalation flow of 300 L/min over a period of 30 s.	Not applicable			-		Not applicable

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Part 7.16 Breathing Resistance	Inhalation 30L/min	0,6 mbar	0,7 mbar	1,0 mbar	See the table below	FFP2	PASS
	Inhalation 95L/min	2,1 mbar	2,4 mbar	3,0 mbar	See the table below	FFP2	PASS
	Exhalation 160L/min	3,0 mbar	3,0 mbar	3,0 mbar	See the table below	FFP2	PASS

Breathing Resistance (mbar)	Inhalation 30L/min	Inhalation 95L/min
As received	0,5	1,7
As received	0,4	1,6
As received	0,4	1,6
After temperature conditioning	0,4	1,6
After temperature conditioning	0,5	1,6
After temperature conditioning	0,4	1,7
After the simulated wearing treatment	0,5	1,6
After the simulated wearing treatment	0,5	1,6
After the simulated wearing treatment	0,5	1,7
After the flow conditioning	-	-
After the flow conditioning	-	-
After the flow conditioning	-	-

Breathing Resistance 160L/min (mbar)	Facing	Facing	Facing	Lying on the	Lying on the

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Table with 6 columns: Test condition, directly ahead, vertically upwards, vertically downwards, left side, right side. Rows include 'As received', 'After temperature conditioning', 'After the simulated wearing treatment', and 'After the flow conditioning'.

Table with 6 columns: TESTS, PARAMETER, PERFORMANCE LEVELS (FFP1, FFP2, FFP3), RESULTS, PERFORMANCE LEVELS, EVALUATION. Rows include 'Part 7.17 Clogging' and 'Part 7.18 Demountable part'.

9. DECISION

Analysis and examinations ROSIMASK RM19930 model coded personal protective equipment; Respiratory Protective Devices EN 149:2001 +A1:2009- Filtered Half Masks for Protection Against Particles - Properties, Experiments and Marking standards are evaluated. The homogeneity of the production was monitored at the performance levels determined as a result of the technical evaluations made within the scope of MODULE C2.



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10. ATTACHMENTS

- Basic Health Safety Requirements
- Risk Assessment
- Test Reports (M-2021-00553)
- User Instruction

Reason for revision : Company information has been revised.

CONTROLLER : ERHAN ÜSTÜNEL

SIGNATURE :

DATE : 23.08.2021