

AB Tip İnceleme Sertifikası EU Type-Examination Certificate

Belge No / Certificate No : 180-21-01-R05
Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /
Certification Date / Certificate Validity Date : 19.05.2021-10.03.2026
Belge Geçerlilik Tarihi / Document Validity Period : 5 yıl / 5 years
Firma Unvanı ve Adresi /
Company Name and Address : PARTEKS DOKUMA GİYİM SAN. VE TİC.
LTD. ŞTİ.
Yunus Emre Mah. Sabır Cad. No:6/2 Sancaktepe/
İSTANBUL

Ürün Adı /Modeller / Product Name / Models : PARMASK PS1001(white)
PARMASK PS2001(black and colors)
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-2021-00340, M-2021-00341, M-2021-00916

Ürün Tipi / Product Type:

- EN 149+ A1 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: PARMASK PS1001, PARMASK PS2001 model ürünleri kumaş, elastik kayış, burun klipsi ve filtre katmanı kullanılarak imal edilmiştir./ PARMASK PS1001, PARMASK PS2001 model products are manufactured using fabric, elastic strap, nose clip, filter layer.

Revizyon nedeni/ Reason for revision: Farklı renkte ürünler eklenmiştir./ Different color products have been added.

Volkan AKIN

19.05.2021

Karar Verici / Approver



Okan AKEL

19.05.2021

Şirket Müdürü / General manager



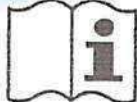
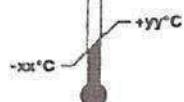
ATTACHMENTS (180-21-01-R05)

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 : PARMASK PS1001, PARMASK PS2001

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: PARTEKS DOKUMA GİYİM SAN. VE TİC. LTD. ŞTİ.	
PPE TYPE :	
- EN 149+ A1 Respiratory protective devices - Filtering half masks to protect against particles	
MODEL: PARMASK PS1001, PARMASK PS2001	
PICTOGRAM AND PERFORMANCE LEVELS:	
EN 149+ A1 FFP2 NR	
 NB 2841	 Year Month yyyy/mm
 yyyy/mm	 -xx°C +yy°C
 < xx % Or Condition of Storage	

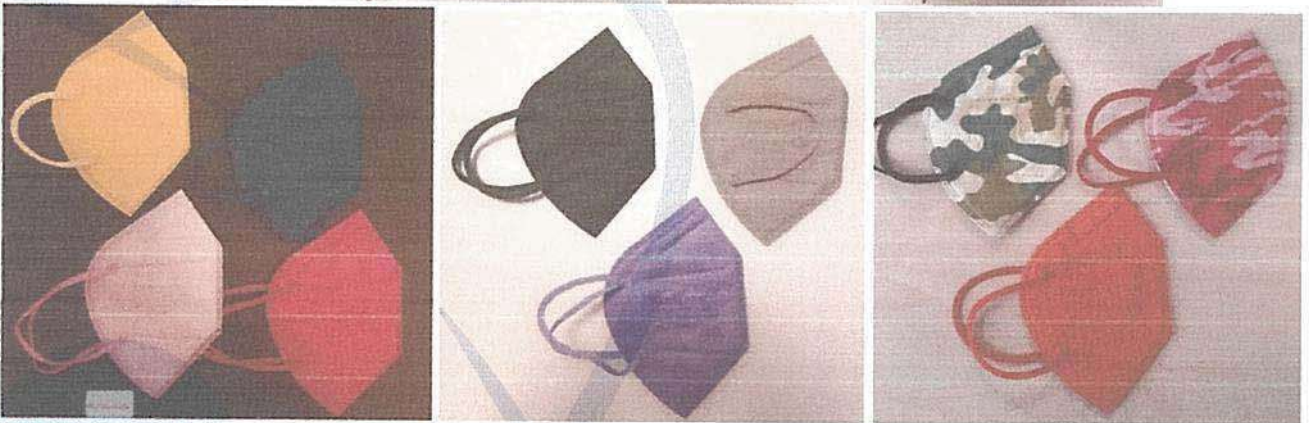
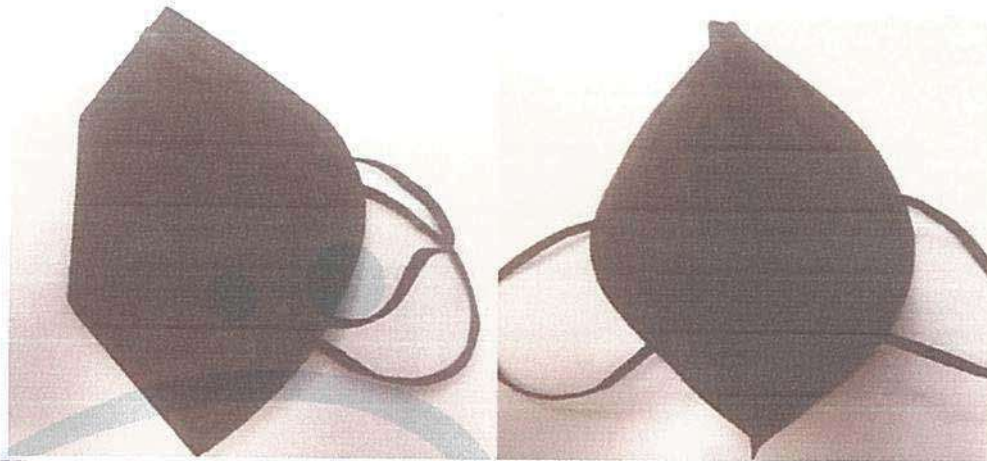
MNA LABORATORIES SAN. TIC. LTD. ŞTİ declares that the above-mentioned product meets the requirements of the directive according to the EU Directive 2016/425, the safety of the product is covered by the conditions and use specified in this certificate and in the technical file.

ATTACHMENTS (180-21-01-R05)

PRODUCT PICTURES



PARMASK PS1001



PARMASK PS2001 (Black, Navi Blue, Gray, Green, Fushsia, Pink, Yellow, Orange, Lilac, Camouflage Green, Camouflage Pink)

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

ATTACHMENTS (180-21-01-R05)**DOCUMENTS IN THE TECHNICAL FILE**

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

Report No : 180-21-01-R05

Report Date : 19.05.2021

Application No : 180-21-01

1. COMPANY INFORMATION:

PARTEKS DOKUMA GİYİM SAN. VE TİC. LTD. ŞTİ.
Yunus Emre Mah. Sabır Cad. No:6/2 Sancaktepe/ İSTANBUL
Tel: 0 216 641 40 70
Mail: info@parteksgiyim.com

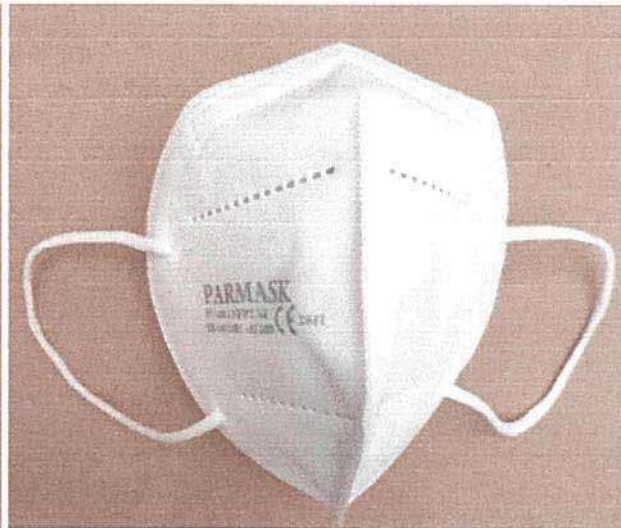
2. PPE INFORMATION:

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

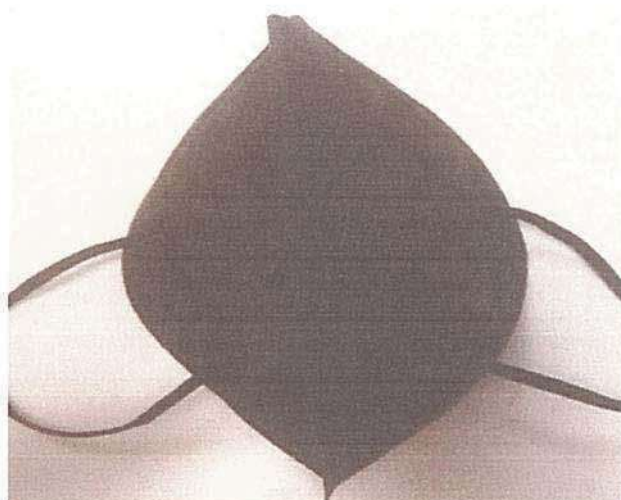
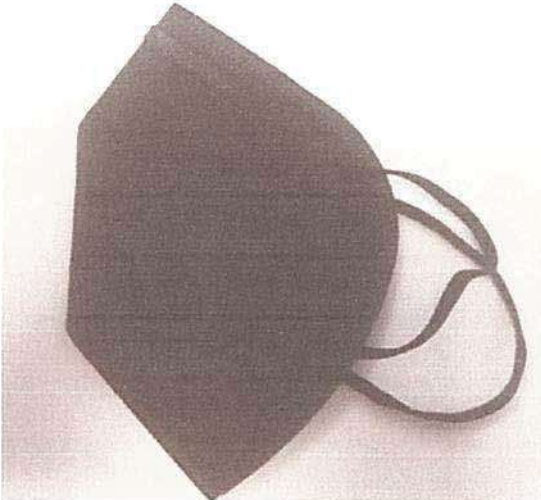
3. PPE TYPE IDENTIFICATION

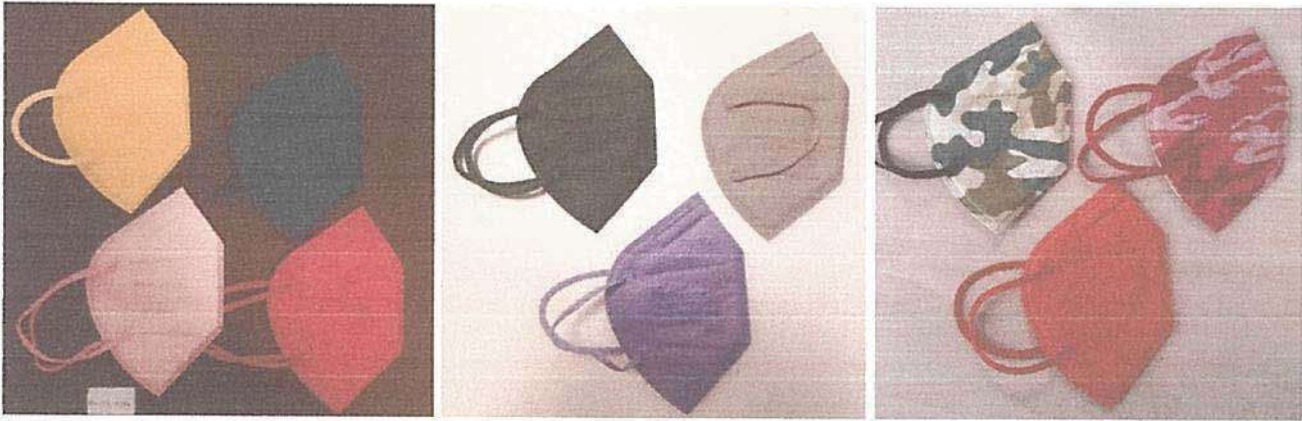
EN 149:2001+A1:2009 Respiratory protective devices – Filtering half masks to protect against particles - Requirements, testing, marking

4. PPE PICTURES



PARMASK PS1001





PARMASK PS2001(Black, Navi Blue, Gray, Green, Fushsia, Pink, Yellow, Orange, Lilac, Camouflage Green Camouflage Pink)

5. PPE DIMENSIONS:

PARMASK PS1001, PARMASK PS2001 model has been found to be produced using standart 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.

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			
Banned Azo Dyes	< 30 mg/kg				< 5 mg/kg (Black, Navi Blue, Gray, Green, Fushsia, Pink, Yellow, Orange, Lilac, Camouflage Green Camouflage Pink)	-	PASS
Part 7.3 Visual inspection	Shall also the marking and the information supplied by the manufacturer				Appropriate	-	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	When conditioned in accordance 8.3.1 &				Appropriate	-	PASS

Material	8.3.2 the particle filter half mask shall not collapse.						
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 (%)						
	Exercise 1	Exercise 2	Exercise 3	Exercise 4	Exercise 5	Average
Subject 1 (As recieved)	8.4	7.4	6.6	8.6	6.9	7.6
Subject 2 (As recieved)	8.1	5.7	6.2	6.9	6.8	6.7
Subject 3 (As recieved)	7.8	9.3	6.3	8.6	9.0	8.2
Subject 4 (As recieved)	7.7	8.4	8.2	8.7	9.2	8.4
Subject 5 (As recieved)	7.5	8.7	8.1	5.8	7.6	7.5
Subject 6 (After temperature conditioning)	7.8	8.1	6.3	6.9	9.1	7.6
Subject 7 (After temperature conditioning)	7.8	8.0	7.7	6.7	7.6	7.6
Subject 8 (After temperature conditioning)	7.9	9.4	7.5	7.6	7.8	8.0
Subject 9 (After temperature conditioning)	6.5	9.0	9.0	8.6	9.2	8.5
Subject 10 (After temperature conditioning)	4.9	4.9	4.9	5.9	4.9	5.1

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	RESULTS	PERFORMANCE	EVALUATION
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		LEVELS				LEVELS	
		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 recieved	4.0	4.3
As recieved	4.4	4.5
As recieved	4.2	4.4
After the simulated wearing treatment	4.6	4.8
After the simulated wearing treatment	4.5	4.6
After the simulated wearing treatment	4.2	4.5
Mechanical strength and temperature conditioning	5.4	5.0
Mechanical strength and temperature conditioning	5.2	5.3
Mechanical strength and temperature conditioning	5.3	5.5

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		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				0,84 0,79 0,83	-	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 recieved	0,6	2,0
As recieved	0,5	2,1
As recieved	0,5	2,0
After temperature conditioning	0,5	2,0
After temperature conditioning	0,6	2,0
After temperature conditioning	0,5	2,1
After the simulated wearing treatment	0,5	2,0
After the simulated wearing treatment	0,6	2,0
After the simulated wearing treatment	0,6	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	2,6	2,6	2,6	2,5	2,6
As recieved	2,5	2,6	2,6	2,5	2,6
As recieved	2,5	2,6	2,6	2,5	2,6
After temperature conditioning	2,5	2,6	2,6	2,6	2,6
After temperature conditioning	2,6	2,6	2,6	2,6	2,6
After temperature conditioning	2,6	2,6	2,6	2,6	2,6
After the simulated wearing treatment	2,6	2,6	2,5	2,6	2,6
After the simulated wearing treatment	2,6	2,6	2,5	2,6	2,6
After the simulated wearing treatment	2,6	2,6	2,6	2,6	2,6

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Part 7.17 Clogging	After clogging the inhalation resistances shall not exceed. (valved)	4 mbar	5 mbar	7 mbar	Not applicable	-	Not applicable
	The exhalation resistance shall not exceed 3 mbar at 160 L/ min continuous flow. (valved)				Not applicable	-	Not applicable
	After clogging the inhalation and exhalation resistances shall not exceed. (valveless)	3 mbar	4 mbar	5 mbar	Not applicable	-	Not applicable
Part 7.18 Demountable part	All demountable parts (if fitted) shall be readily connected and secured were possible by hand.				Not applicable	-	Not applicable

9. DECISION PROPOSAL

Analysis and examinations PARMASK PS1001, PARMASK PS2001 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

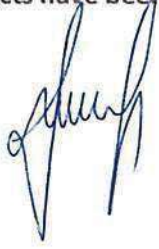
- Basic Health Safety Requirements
- Risk Assessment
- User Instruction

Reason for revision : Different products have been added.

CONTROLLER : VOLKAN AKIN

SING :

DATE : 19.05.2021



Notified Body Number: 2841 (MODULE C2, ANNEX VII) (180-21-01-R04-01-R01)

Report No : 180-21-01-R04-01-R01

Report Date : 19.05.2021

Application No : 180-21-01-R04-01

1. COMPANY INFORMATION:

PARTEKS DOKUMA GİYİM SAN. VE TİC. LTD. ŞTİ.

Yunus Emre Mah. Sabır Cad. No:6/2 Sancaktepe/ İSTANBUL

Tel: 0 216 641 40 70

Mail: info@parteksgiyim.com

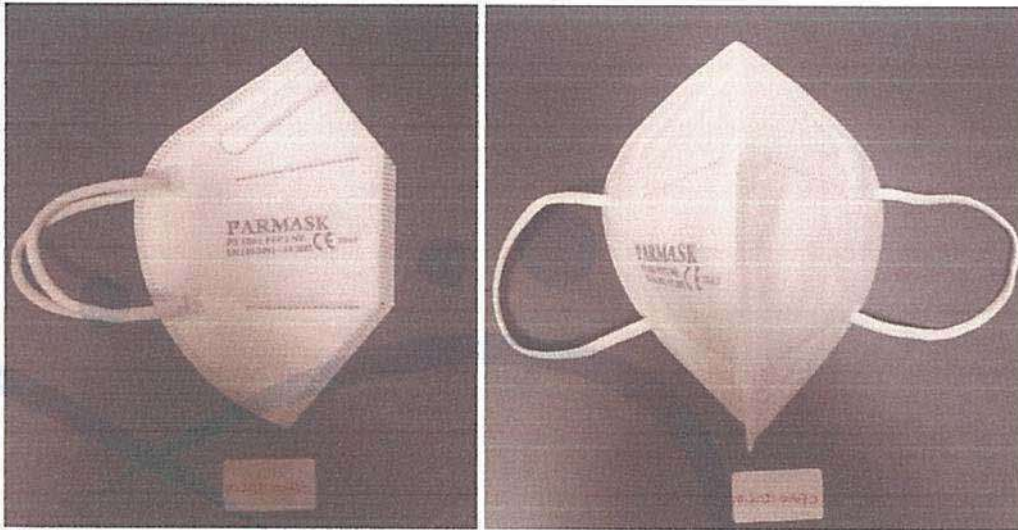
2. PPE INFORMATION:

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

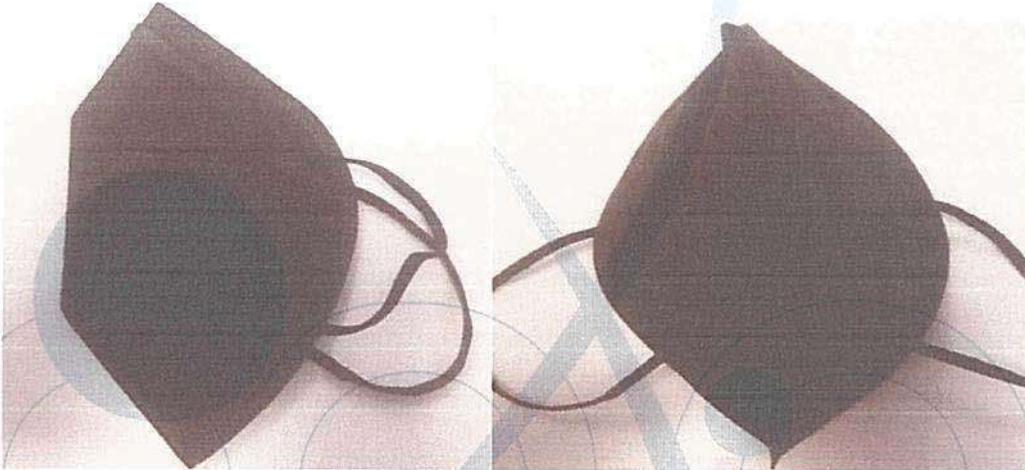
3. PPE TYPE IDENTIFICATION

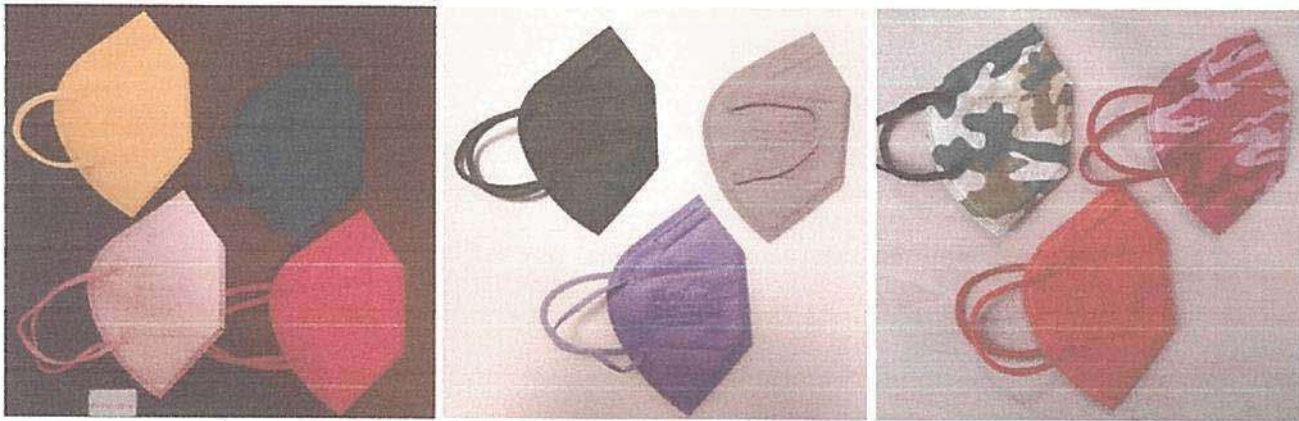
EN 149:2001+A1:2009 Respiratory protective devices – Filtering half masks to protect against particles - Requirements, testing, marking

4. PPE PICTURES



PARMASK PS1001





PARMASK PS2001(Black, Navi Blue, Gray, Green, Fushsia, Pink, Yellow, Orange, Lilac, Camouflage Green ,Camouflage Pink)

5. PPE DIMENSIONS:

PARMASK PS1001, PARMASK PS2001 model has been found to be produced using standart sizes.

6. PPE PRODUCT MATERIAL INFORMATION:

The product is made of elastic strap, nonwoven fabric on the outer and inner layers and fitler 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.

8. ANALYSIS AND EVALUATIONS:

EN 149:2001 +A1:2009

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Banned Azo Dyes	< 30 mg/kg				< 5 mg/kg (Black, Navi Blue, Gray, Green, Fushsia, Pink, Yellow, Orange, Lilac, Camouflage Green ,Camouflage Pink)		PASS
Part 7.3 Visual inspection	Shall also the marking and the information supplied by the manufacturer				Appropriate	-	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	When conditioned in accordance 8.3.1 &				Appropriate	-	PASS

Material	8.3.2 the particle filter half mask shall not collapse.			
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 (%)						
	Exercise 1	Exercise 2	Exercise 3	Exercise 4	Exercise 5	Average
Subject 1 (As recieved)	8.2	7.2	6.4	8.4	6.7	7.4
Subject 2 (As recieved)	7.9	5.5	6.0	6.7	6.6	6.5
Subject 3 (As recieved)	7.6	8.8	6.1	8.4	8.8	7.9
Subject 4 (As recieved)	7.5	8.2	8.0	8.5	8.8	8.2
Subject 5 (As recieved)	7.3	8.5	7.9	5.6	7.4	7.3
Subject 6 (After temperature conditioning)	7.6	7.9	6.1	6.7	8.9	7.4
Subject 7 (After temperature conditioning)	7.6	7.8	7.5	6.5	7.4	7.4
Subject 8 (After temperature conditioning)	7.7	8.8	7.3	7.4	7.6	7.8
Subject 9 (After temperature conditioning)	6.3	8.8	8.8	8.4	9.0	8.3
Subject 10 (After temperature conditioning)	4.7	4.7	4.7	5.7	4.7	4.9

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 recieved	3.9	4.2
As recieved	4.2	4.5
As recieved	4.2	4.4
After the simulated wearing treatment	4.2	4.4
After the simulated wearing treatment	4.1	4.6
After the simulated wearing treatment	4.2	4.5
Mechanical strength and temperature conditioning	5.1	5.2
Mechanical strength and temperature conditioning	5.0	5.0
Mechanical strength and temperature conditioning	5.0	5.1

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		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				0,88 0,84 0,83	-	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 recieved	0,6	2,2
As recieved	0,6	2,2
As recieved	0,5	2,3
After temperature conditioning	0,5	2,3
After temperature conditioning	0,6	2,3
After temperature conditioning	0,5	2,2
After the simulated wearing treatment	0,5	2,3
After the simulated wearing treatment	0,6	2,3
After the simulated wearing treatment	0,6	2,3

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	2,8	2,8	2,8	2,9	2,8
As recieved	2,9	2,8	2,8	2,9	2,8
As recieved	2,9	2,8	2,8	2,9	2,8
After temperature conditioning	2,9	2,8	2,8	2,8	2,8
After temperature conditioning	2,8	2,8	2,8	2,8	2,8
After temperature conditioning	2,8	2,8	2,8	2,8	2,8
After the simulated wearing treatment	2,8	2,8	2,9	2,8	2,8
After the simulated wearing treatment	2,8	2,8	2,9	2,8	2,8
After the simulated wearing treatment	2,8	2,8	2,8	2,8	2,8

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Part 7.17 Clogging	After clogging the inhalation resistances shall not exceed. (valved)	4 mbar	5 mbar	7 mbar	Not applicable	-	Not applicable
	The exhalation resistance shall not exceed 3 mbar at 160 L/ min continuous flow. (valved)				Not applicable	-	Not applicable
	After clogging the inhalation and exhalation resistances shall	3 mbar	4 mbar	5 mbar	Not applicable	-	Not applicable

	not exceed. (valveless)						
Part 7.18 Demountable part	All demountable parts (if fitted) shall be readily connected and secured where possible by hand.				Not applicable	-	Not applicable

9. DECISION

Analysis and examinations PARMASK PS1001, PARMASK PS2001 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.

10. ATTACHMENTS

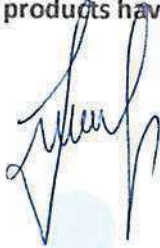
- Basic Health Safety Requirements
- Risk Assessment
- Test Reports (M-2021-00670, M-2021-00916)
- User Instruction

Reason for revision : Different color products have been added.

CONTROLLER : VOLKAN AKIN

SIGN :

DATE : 19.05.2021



EC DECLARATION OF CONFORMITY AT UYGUNLUK BEYANI



UYGUNLUK BEYANI

İMALATÇI/MANUFACTURER

PARTEKS DOKUMA GİYİM SAN ve TİC. LTD. ŞTİ.

Yunus Emre Mah. Sabır Cad. No:6/2

Sancaktepe/İSTANBUL/TÜRKİYE

İLGİLİ DİREKTİF/Related Directive

2016/425/AT Kişisel Koruyucu Donanım Yönetmeliği

2016/425/EU Personal Protective Equipment (PPE)

ÜRÜN ADI/Product Name

**Koruyucu Maske Protective Mask
(FFP2 NR)**

Model No/Models Number

WHITE-PS1001, BLACK-PS2001

MARKA/Trade Mark

PARMASK

İLGİLİ STANDARTLAR/Standarts Applied

EN 149, EN ISO 9001

Ürünlerimizin uyumlaştırılmış standartlara göre üretildiğini ve 2016/425/AT Kişisel Koruyucu Donanım Yönetmeliği hükümlerine uygun olduğunu beyan ederiz.

Destekleyici tüm belgeler firmamızda bulunmaktadır.

We declare that our products are manufactured according to harmonized standards and comply with the provisions of the 2016/425/EU Personal Protective Equipment Directive.

All supporting documents are available in our company.

The PPE is subject to the conformity assessment procedure to type based on internal production control plus supervised product checks at random intervals (Module B) under surveillance of the Notified body which performed the EU Type- examination and issued EU type-examination certificate:

MNA CERTIFICATION- 2841

CERTIFICATE NO- 180-21-01-R04

Name, date and place of issue:

Abdullah ALAN - 30.03.2021, İstanbul-TÜRKİYE

Sign- Stamp:

**PARTEKS DOKUMA GİYİM
SANAYİ VE TİCARET LİMİTED ŞİRKETİ**
Yunus Emre Mah. Sabır Cad. No:6/2
Sancaktepe/İST. T.C. Sic.No:110950-5
SULTANBEY İ.V.D.:722 073 8427

30.03.2021

TO PARTEKS DOKUMA GİYİM SAN. VE TİC. LTD. ŞTİ.;

Your certificate with code 180-21-01-R04 has been issued and are still valid. Your request has been received for Module C2. Your process will be planned and carried out as soon as possible. Afterwards, your technical evaluation report will be shared at the end of assessments.

Laboratory Manager

Volkan AKIN

**MNA LABORATUVARLAR
SAN TİC.LTD.ŞTİ.**

Küçükbakkalköy Mah Yenidoğan Caddesi
No:21 Alışveriş / İSTANBUL
Tel (0216) 574 07 08 Fax:(0216) 575 13 31
Kağıt taşı: V.D. 023 030 7322
Tic Sic No 731 989

KIOSCERT®
CERTIFICATE

Bu Sertifika / This certificate is granted to the organization

**PARTEKS DOKUMA GİYİM SANAYİ
VE TİCARET LİMİTED ŞİRKETİ**

Yunus Emre Mah. Sabır Cad. No:6/2 Sancaktepe / İstanbul / Türkiye

KIOSCERT Belgelendirme tarafından denetlenmiş ve uygulamakta olduğu
Kalite Yönetim Sisteminin

Is audited by KIOSCERT Certification and applied
Quality Management System meet the requirements of

ISO 9001:2015

standardına aşağıdaki kapsamda uymakta olduğu gözlenmiştir.

Standard for the following activities.

Belgelendirme Kapsamı / Certification Scope

TEKSTİL ÜRÜNLERİ, DIŞ GİYİMLERİN VE TEKSTİL MALZEMESİNDEN YAPILAN
TEK KULLANIMLIK MASKE ÜRETİMİ VE SATIŞI

TEXTILE PRODUCTS, SINGLE USE MADE FROM OUTER GARMENTS AND
TEXTILE MATERIAL PRODUCTION AND SALE OF MASKS

Sertifika Yayın Tarihi / 30.03.2020

Certificate Date

Sertifika Son Basım Tarihi / 29.03.2021

Certificate Last Issue Date

Belge Periyodu / 3 Yıl (Years)

Certificate Period

Sertifika Geçerlilik Tarihi / 29.03.2022

Certificate validity Date

Sertifika No / QMS-20-3003-PAR

Certificate No



KIOSCERT®
CERTIFICATE

Bu Sertifika / This certificate is granted to the organization

**PARTEKS DOKUMA GİYİM SANAYİ
VE TİCARET LİMİTED ŞİRKETİ**

Yunus Emre Mah. Sabır Cad. No:6/2 Sancaktepe / İstanbul / Türkiye

KIOSCERT Belgelendirme tarafından denetlenmiş ve uygulamakta olduğu

Medikal Cihaz Yönetim Sisteminin

Is audited by KIOSCERT Certification and applied

Medical Devices Management System meet the requirements of

ISO 13485:2016

standardına aşağıdaki kapsamda uymakta olduğu gözlenmiştir.

Standard for the following activities.

Belgelendirme Kapsamı / Certification Scope

TEKSTİL ÜRÜNLERİ, DIŞ GİYİMLERİN VE TEKSTİL MALZEMESİNDEN YAPILAN

• TEK KULLANIMLIK MASKE ÜRETİMİ VE SATIŞI

TEXTILE PRODUCTS, SINGLE USE MADE FROM OUTER GARMENTS AND

TEXTILE MATERIAL PRODUCTION AND SALE OF MASKS

Sertifika Yayın Tarihi / 30.03.2020

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Sertifika Son Basım Tarihi / 29.03.2021

Certificate Last Issue Date

Belge Periyodu / 3 Yıl (Years)

Certificate Period

Sertifika Geçerlilik Tarihi / 29.03.2022

Certificate validity Date

Sertifika No / MDMS-20-3003-PAR

Certificate No



FARMADATI ITALIA Srl
Via S. Francesco, 8
29121 PIACENZA



Ufficio Parafarmaco
Tel. 0523 336933
Fax 0523 336667
parafarmaco@farmadati.it

L'Ufficio PARAFARMACO è a Vs disposizione dal lunedì al venerdì (8:30 -18:30) per: attribuzione codici paraf, aggiornamento anagrafica prodotti e prezzi e consulenza e informazioni.

Nella Tabella sono riportati i codici base 10 e base 32 attribuiti ai prodotti per l'elaborazione del Barcode tipo 39 in base 32.

N.B. nel codice base 32 non sono utilizzabili le lettere: A,E,I,O. I codici paraf notificati con il presente modulo sono univoci e validi per tutto il territorio nazionale. La variazione della grammatura o della descrizione del prodotto, comporta l'attribuzione di un nuovo paraf.

Codice base 10	Codice base 32	Codice a barre	Codice EAN	Descrizione prodotto	Ditta	Codice articolo (ditta)	Iva	Prezzo al pubblico indicativo	Data prezzo al pubblico	Data inizio commercio
982452334	X8Y23G		8682773361780	MASCHERINA FFP2 PS1001 BI 10PZ	PARTEKS DOKUMA G.S.V.T.LTD.STI	PS1001	5	20,00	01/04/2021	
982452385	X8Y251		8682773361728	MASCHERINA FFP2 PS2001 NE 10PZ	PARTEKS DOKUMA G.S.V.T.LTD.STI	PS2001	5	20,00	01/04/2021	

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Codice base 10	Codice base 32	Codice a barre	Codice EAN	Descrizione prodotto	Ditta	Codice articolo (ditta)	Iva	Prezzo al pubblico indicativo	Data prezzo al pubblico	Data inizio commercio
982461232	X8YBTJ		8683220346176	MASCHERINA FFP2 PS1001 BI 1PZ	PARTEKS DOKUMA G.S.V.T.LTD.STI	PS1001	5	2,00	01/04/2021	
982461244	X8YBTW		8683220346121	MASCHERINA FFP2 PS2001 NE 1PZ	PARTEKS DOKUMA G.S.V.T.LTD.STI	PS2001	5	2,00	01/04/2021	

RAPPORTO DI PROVA N° 25_02/04/21

Data emissione 02/04/2021

A CHI DI COMPETENZA

Tipo campione	Materiali
Data ricevimento campione	29/03/2021
Descrizione campione	PARMASK PS1001 FFP2 NR ¹
Punto di campionamento	Presso la sede del Committente ¹
Campionatore	Committente ¹
Metodo di campionamento	Interno al Committente ^{1**}
Confezione campione	Campione confezionato in sacchetto di plastica
Condizione del campione/Sigilli	Campione consegnato in modalità e quantità idonee all'esecuzione delle indagini analitiche richieste.
Trasporto a cura di	Cliente
Temperatura	---

Protocollo Campione 01_300321 del 30/03/21

Descrizione PARMASK PS1001 FFP2 NR

Indagine eseguita	Risultato	U.M	Metodo	Limiti	Rif.
Data inizio prova- Data fine prova					
Efficienza di filtrazione batterica (BFE)	99,9	%	UNI EN 14683:2019 App B	≥95 ≥98 ≥98	14683
30/03/21 -01/04/21					
Controllo Negativo	0	UFC			
1) Controllo Positivo	986	UFC			
2) Controllo Positivo	1022	UFC			
1) BFE	100	%		≥95 ≥98 ≥98	14683
2) BFE	100	%		≥95 ≥98 ≥98	14683
3) BFE	99,9	%		≥95 ≥98 ≥98	14683
4) BFE	99,9	%		≥95 ≥98 ≥98	14683
5) BFE	99,9	%		≥95 ≥98 ≥98	14683

Informazioni accessorie

Sono state eseguite determinazioni su 5 provini, tagliati da maschere complete/tessuto originale che compone la maschera.

Ogni provino ha dimensione 100 mm × 100 mm e comprende tutti gli strati della maschera nell'ordine in cui sono inseriti nella maschera completa.

Ogni provino è condizionato a (21 ± 5) °C e (85 ± 5)% di umidità relativa per almeno 4 ore.

La prova è eseguita con l'interno della maschera, rivolto verso la preparazione batterica di prova.

L'area di prova ha dimensione 49 cm².

La portata durante la prova è pari a 28,3l/min.

Il valore finale della prova è dato dal risultato di BFE più basso riscontrato nelle prove eseguite.

Efficienza di filtrazione delle polveri del materiale filtrante (PFE)*	96,49	%	PP-80:2020 rev.0	≥80 ≥94 ≥99	UNI149
30/03/21 -30/03/21					
PFE _provino 1	96,2	%			
PFE _provino 2	96,7	%			
PFE _provino 3	95,9	%			
PFE _provino 4	96,4	%			
PFE _provino 5	96,8	%			

M18-2 Rev.2 09/03/2021

Artea Srl Unipersonale - Via Piana Sn - 82030 Ponte Bn - Tel/Fax 0824 874 510

e-mail: info@artearsl.eu – Pec: artearsl@registerpec.it; Courtesy Page: www.artearsl.eu

Capitale sociale € 25000,00 i.v. - P. IVA e CF 01401230626 – Iscritta al Registro delle imprese di Benevento n. REA BN 117373

SEGUE RAPPORTO DI PROVA N° 25_02/04/21

Data emissione 02/04/2021

Indagine eseguita	Risultato	U.M	Metodo	Limiti	Rif.
Data inizio prova- Data fine prova					
PFE _ provino 6	97,0	%			
PFE _ provino 7	96,6	%			
PFE _ provino 8	95,8	%			
PFE _ provino 9	97,1	%			
PFE _ provino 10	96,4	%			

Informazioni accessorie

Prova eseguita con MAS-Q-CHECK della PALAS.

La percentuale espressa è l'efficienza di filtrazione in numero di particelle da 0,1 µm a 10 µm.

Flusso operativo di lavoro 95 l/min.

(*) Prova non accreditata da ACCREDIA

(**) Campionamento non oggetto di accreditamento ACCREDIA

(†) Informazione fornita da cliente, il laboratorio ne declina ogni responsabilità.

Note legislative

(14683) = UNI EN 14683:2019 Maschere facciali ad uso medico - Requisiti e metodi di prova - Tabella 1 "Requisiti prestazionali per maschere ad uso medico".

I = mascherina medica facciale di Tipo I

II = mascherina medica facciale di Tipo II

IIR = mascherina medica facciale di Tipo IIR

(UNI149) = UNI EN 149:2009 Dispositivi di protezione delle vie respiratorie - Semimaschere filtranti antipolvere - Requisiti, prove, marcatura.

FFP1 = maschere respiratorie della classe di protezione FFP1

FFP2 = maschere respiratorie della classe di protezione FFP2

FFP3 = maschere respiratorie della classe di protezione FFP3

Dichiarazione di Conformità

Per i parametri analizzati, secondo la norma UNI EN 149:2009, il campione è conforme alle caratteristiche prestazionali previste per le Maschere respiratorie della classe di protezione FFP2

I risultati contenuti nel presente Rapporto si riferiscono esclusivamente al campione così come pervenuto in laboratorio

I risultati si riferiscono esclusivamente al campione testato e non implicano una approvazione di lotto o partite intere; nel caso in cui sia il Cliente responsabile della fase di Campionamento, i risultati si riferiscono al campione così come ricevuto. Il Laboratorio declina la propria responsabilità sui risultati calcolati considerando i dati di campionamento forniti dal Cliente.

I campioni vengono conservati presso questo laboratorio fino a completamento delle prove, ad esclusione dei campioni ufficiali.

Le incertezze associate ai risultati delle prove sono state calcolate con un fattore di copertura k=2 pari ad un livello di fiducia del 95%.

Nel caso in cui sia formulata una dichiarazione di conformità, ai fini dell'accettabilità del dato analitico rispetto ad un valore limite/valore guida non si tiene conto dell'incertezza estesa e/o intervallo di confidenza stimati.

E' fatto assoluto divieto di modificare anche parzialmente i dati contenuti.

U.M = Unità di misura LOQ = Limite di quantificazione Rif.= Riferimento normativo PP= Metodo interno (Procedura di prova)

E' vietata la riproduzione totale o parziale della presente copia, salvo autorizzazione scritta da parte del laboratorio

Fine Rapporto di Prova

Il Direttore Tecnico

Dott. Giuseppe Mazza

Documento firmato digitalmente dal
Dott. Giuseppe Mazza -Ordine dei
Chimici della Campania N.1147

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982881258	X9C4ZB		8683220346534	MASCHERINA FFP2 PS2001 ARA10PZ	PARTEKS DOKUMA G.S.V.T.LTD.STI	PS2001	5	25,00	08/06/2021	08/06/2021
982881260	X9C4ZD		8683220346541	MASCHERINA FFP2 PS2001 ARA1PZ	PARTEKS DOKUMA G.S.V.T.LTD.STI	PS2001	5	2,50	08/06/2021	08/06/2021
982881272	X9C4ZS		8683220346190	MASCHERINA FFP2 PS2001 BL N10P	PARTEKS DOKUMA G.S.V.T.LTD.STI	PS2001	5	25,00	08/06/2021	08/06/2021
982881284	X9C504		8683220346411	MASCHERINA FFP2 PS2001 BL N1PZ	PARTEKS DOKUMA G.S.V.T.LTD.STI	PS2001	5	2,50	08/06/2021	08/06/2021
982881296	X9C50J		8683220346459	MASCHERINA FFP2 PS2001 CA R10P	PARTEKS DOKUMA G.S.V.T.LTD.STI	PS2001	5	25,00	08/06/2021	08/06/2021
982881308	X9C50W		8683220346497	MASCHERINA FFP2 PS2001 CA R1PZ	PARTEKS DOKUMA G.S.V.T.LTD.STI	PS2001	5	2,50	08/06/2021	08/06/2021
982881310	X9C50Y		8683220346442	MASCHERINA FFP2 PS2001 CA V10P	PARTEKS DOKUMA G.S.V.T.LTD.STI	PS2001	5	25,00	08/06/2021	08/06/2021
982881322	X9C51B		8683220346480	MASCHERINA FFP2 PS2001 CA V1PZ	PARTEKS DOKUMA G.S.V.T.LTD.STI	PS2001	5	2,50	08/06/2021	08/06/2021
982881334	X9C51Q		8683220346527	MASCHERINA FFP2 PS2001 FUC 1PZ	PARTEKS DOKUMA G.S.V.T.LTD.STI	PS2001	5	2,50	08/06/2021	08/06/2021
982881346	X9C522		8683220346510	MASCHERINA FFP2 PS2001 FUC10PZ	PARTEKS DOKUMA G.S.V.T.LTD.STI	PS2001	5	25,00	08/06/2021	08/06/2021
982881359	X9C52H		8683220346213	MASCHERINA FFP2 PS2001 GI 10PZ	PARTEKS DOKUMA G.S.V.T.LTD.STI	PS2001	5	25,00	08/06/2021	08/06/2021
982881361	X9C52K		8683220346428	MASCHERINA FFP2 PS2001 GI 1PZ	PARTEKS DOKUMA G.S.V.T.LTD.STI	PS2001	5	2,50	08/06/2021	08/06/2021
982881373	X9C52X		8683220346466	MASCHERINA FFP2 PS2001 GRI 1PZ	PARTEKS DOKUMA G.S.V.T.LTD.STI	PS2001	5	2,50	08/06/2021	08/06/2021
982881385	X9C539		8683220346220	MASCHERINA FFP2 PS2001 GRI10PZ	PARTEKS DOKUMA G.S.V.T.LTD.STI	PS2001	5	25,00	08/06/2021	08/06/2021

Codice base 10	Codice base 32	Codice a barre	Codice EAN	Descrizione prodotto	Ditta	Codice articolo (ditta)	Iva	Prezzo al pubblico indicativo	Data prezzo al pubblico	Data inizio commercio
982881397	X9C53P		8683220346558	MASCHERINA FFP2 PS2001 LIL10PZ	PARTEKS DOKUMA G.S.V.T.LTD.STI	PS2001	5	25,00	08/06/2021	08/06/2021
982881409	X9C541		8683220346565	MASCHERINA FFP2 PS2001 LIL1PZ	PARTEKS DOKUMA G.S.V.T.LTD.STI	PS2001	5	2,50	08/06/2021	08/06/2021
982881411	X9C543		8683220346183	MASCHERINA FFP2 PS2001 RA 10PZ	PARTEKS DOKUMA G.S.V.T.LTD.STI	PS2001	5	25,00	08/06/2021	08/06/2021
982881423	X9C54H		8683220346404	MASCHERINA FFP2 PS2001 RA 1PZ	PARTEKS DOKUMA G.S.V.T.LTD.STI	PS2001	5	2,50	08/06/2021	08/06/2021
982881435	X9C54V		8683220346435	MASCHERINA FFP2 PS2001 VE S10P	PARTEKS DOKUMA G.S.V.T.LTD.STI	PS2001	5	25,00	08/06/2021	08/06/2021
982881447	X9C557		8683220346473	MASCHERINA FFP2 PS2001 VE S1PZ	PARTEKS DOKUMA G.S.V.T.LTD.STI	PS2001	5	2,50	08/06/2021	08/06/2021