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Convenzionato con la Regione Calabria
Convenzione n. 2349 del 4 Maggio 1998

BLS

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Confezionate **Singolarmente**

Certificata CE

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Capitale sociale: € 100.000,00 i.v. - Partita **IVA 01352180796** - C.F. **05884370585** R.E.A. CZ 113188

MAXPO

B|BRAUN SHARING EXPERTISE
DISTRIBUTORE CALABRIA & SICILIA

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Convenzione n. 2349 del 4 Maggio 1998

BLS

N. _____ Data: __/__ /2021

CLIENTE FATTURAZIONE

Cognome : _____ **Nome :** _____

Ragione Sociale del Cliente : _____

Indirizzo : _____

Comune : _____ **Cap:** _____

Telefono : _____

E-Mail : _____

P. IVA : _____

C. Fiscale : _____

Codice UNIVOCO : _____

PEC : _____

CONDIZIONI DI PAGAMENTO :

□ **Pagamento a ricezione merce e fattura.**

□ **Bonifico anticipato, se soggetto privato**

COD. PROD.	DESCRIZIONE ARTICOLO	QT.

Autorizzo il trattamento dei dati personali in base all'art. 13 del D. Lgs. 196/2003 e all'art. 13 GDPR 679/16.

(Timbro e firma)

L'accettazione della presente commissione si intende salvo approvazione della casa.
La merce viaggia a rischio e pericolo del cliente anche se venduta salvo destino .
I dati del cliente sono trattati nel rispetto del D.LGS. 196-2003.
Aggiornato con nuovo D.lgs. 101/2018

MNA LABORATUVARLARI

Notified Body Number: 2841

AB Tip İnceleme Sertifikası
EU Type-Examination Certificate

Belge No / ***Certificate No***	: 180-21-01-R04
Belgelendirme Tarihi - Bir Sonraki Belge Tarihi / ***Certification Date / Certificate Validity Date***	: 30.03.2021-10.03.2026
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)
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-2021-00340, M-2021-00341

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:*** Siyah ürün için model adı eklenmiştir./ *The model name has been added for the black product..*

Volkan AKIN	***Okan AKEL***
30.03.2021	***30.03.2021***
Karar Verici / Approver	***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 (180-21-01-R04)

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.

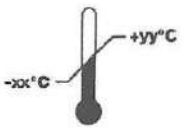
PPE TYPE :

- 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

CE
NB 2841



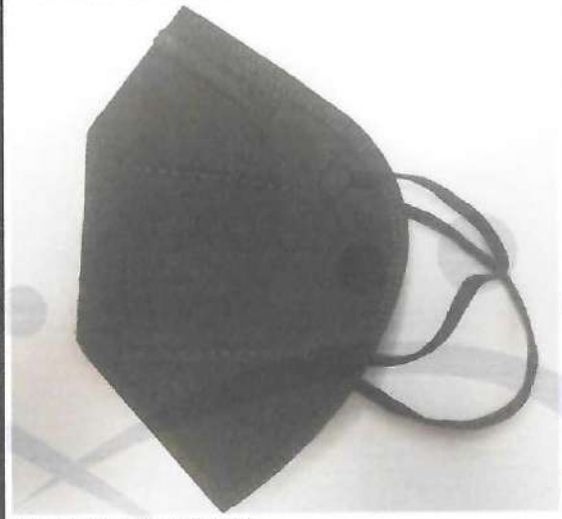
Or Condition of Storage

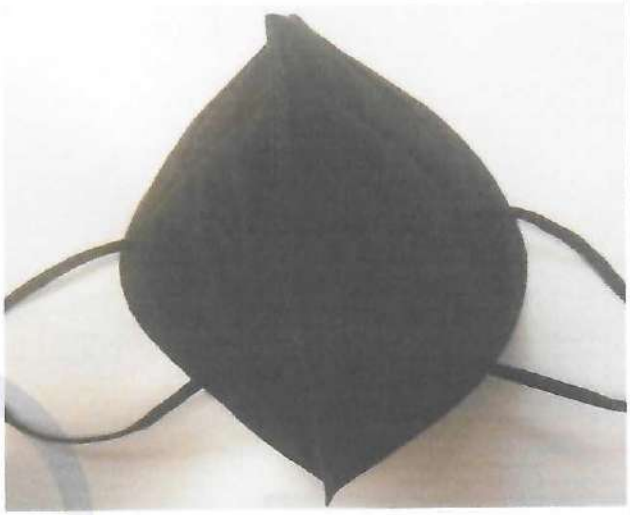
MNA LABORATORIES SAN. TIC. LTD. ŞTİ declares that the above-mentioned product meets the requirements of the directive according to the EU Directive 2016/425, the safety of the product is covered by the conditions and use specified in this certificate and in the technical file.

ATTACHMENTS (180-21-01-R04)

PRODUCT PICTURES

PARMASK PS1001





PARMASK PS2001

DOCUMENTS IN THE TECHNICAL FILE

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

Report No : 180-21-01-R04

Report Date : 30.03.2021

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 fitler 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

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	-	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 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 (%)					
	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 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	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
- Test Reports
- User Instruction

Reason for revision : **The model name has been added for the black product.**

CONTROLLER : **VOLKAN AKIN**

SING :

DATE : **30.03.2021**

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
WHİTE-PS1001, BLACK-PS2001

MARKA/Trade Mark
PARMASK

İLGİLİ STANDARTLAR/Standarts Applıed

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

CERTİFİCATE 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 Tic.Sic.No: 110950-5
SULTANBEYLİ V.D :722 073 8127

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 Cad
No:21 Ataşehir / İSTANBUL
Tel (0216) 574 07 08 Fax:(0216) 576 13 51
Kozyatağı V.D. 023 030 7322
Tic.Sic.No 731 989

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KIOSCERT®

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Bu Sertifika / This certificate is granted to the organization

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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.

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TEKSTİL ÜRÜNLERİ, DIŞ GİYSİLERİN 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

NAC
MANAGEMENT SYSTEM
ISO/IEC 17021-1:2015
NAC-004-MS

Certification KIOSCERT® Services

Kioscert Uluslararası Sistem Ürün Belgelendirme Denetim ve Eğitim Hizmetleri Ltd. Şti.
İmbatlı Mah. 6076/3 Sk. No: 9 K:2 D:4 Family Park-2 Sitesi Karşıyaka - İZMİR • Tel: 0232 570 08 89 • www.kioscert.com • info@kioscert.com
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Yunus Emre Mah. Sabır Cad. No:6/2 Sancaktepe / İstanbul / Türkiye

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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 GİYSİLERİN VE TEKSTİL MALZEMESİNDEN YAPILAN
TEK KULLANIMLIK MASKE ÜRETİMİ VE SATIŞI

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Sertifika Yayın Tarihi / 30.03.2020
Certificate Date

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Certificate Last Issue Date

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Certificate Period

Sertifika Geçerlilik Tarihi / 29.03.2022
Certificate validity Date

Sertifika No / MDMS-20-3003-PAR
Certificate No

NAC
MANAGEMENT SYSTEM
ISO/IEC 17021-1:2015
NAC-004-MS

Certification KIOSCERT Services

Kioscert Uluslararası Sistem Ürün Belgelendirme Denetim ve Eğitim Hizmetleri Ltd. Şti.
İmbatlı Mah. 6076/3 Sk. No: 9 K:2 D:4 Family Park-2 Sitesi Karşıyaka - İZMİR • Tel: 0232 570 08 89 • www.kioscert.com • info@kioscert.com
Sertifikaların geçerlilik bilgisini **www.kioscert.com** adresinden kontrol edebilirsiniz.

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	

FARMADATI ITALIA Srl
Via S. Francesco, 8
29121 PIACENZA

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

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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
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	

ARIA - TERRA - ENERGIA - ACQUA
ARTEA

Azienda con Sistema di Gestione Certificato UNI EN ISO 9001:2015 e UNI EN ISO 14001:2015. Laboratorio n. 111 BN iscritto nel registro regionale dei laboratori di analisi che effettuano prove analitiche relative all'autocontrollo DDGRC n. 50 del 29/04/2015. Laboratorio di prova conforme ai requisiti della norma UNI CEI EN ISO/IEC 17025. Direttore Tecnico Dott. Giuseppe Mazza – Iscritto all'Ordine dei Chimici della Campania n. 1147

ACCREDIA L'ENTE ITALIANO DI ACCREDITAMENTO

LAB N° 1586

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 *Data inizio prova- Data fine prova*	**Risultato**	**U.M**	**Metodo**	**Limiti**	**Rif.**
Efficienza di filtrazione batterica (BFE) *30/03/21 -01/04/21*	99,9	%	UNI EN 14683:2019 App B	|≥95|≥98|≥98	14683
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)* *30/03/21 -30/03/21*	96,49	%	PP-80:2020 rev.0	|≥80 |≥94 |≥99	UNI149
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

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

Data emissione 02/04/2021

Indagine eseguita *Data inizio prova- Data fine prova*	Risultato	U.M	Metodo	Limiti	Rif.
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

(1) 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 cosi 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'incertezz 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)

---------- ***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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e-mail: info@arteasrl.eu – Pec: arteasrl@registerpec.it ; Courtesy Page: www.arteasrl.eu
Capitale sociale € 25000,00 i.v. - P. IVA e CF 01401230626 – Iscritta al Registro delle imprese di Benevento n. REA BN 117373

Notified Body Number: 2841

CONFORMITY TO TYPE BASED ON INTERNAL PRODUCTON CONTROL PLUS SUPERVISED PRODUCT CHECK AT RANDOM INTERVALS (MODULE C2, ANNEX VII) (180-21-01-R04-01)

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

Report Date :20.04.2021

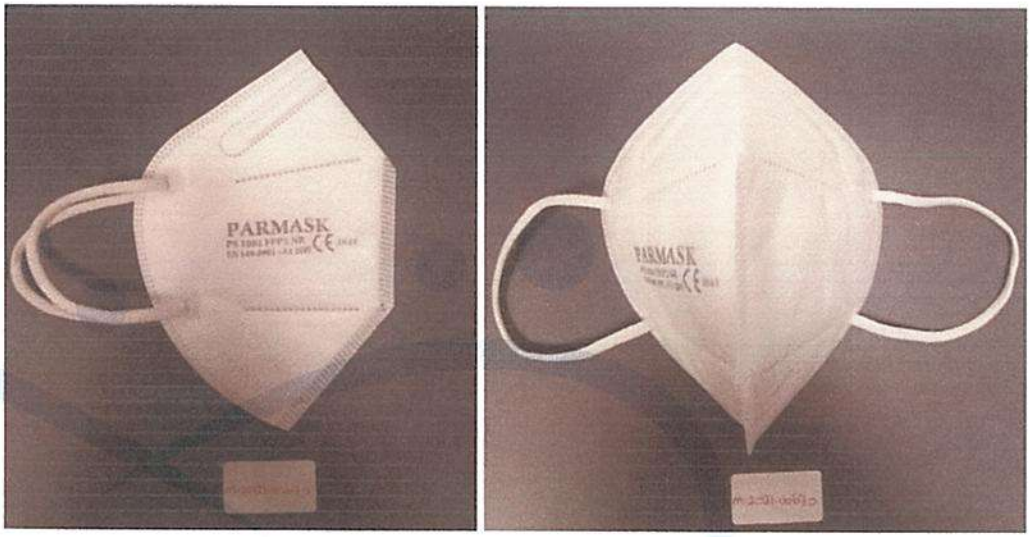
Application No :180-21-01-R04-01

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

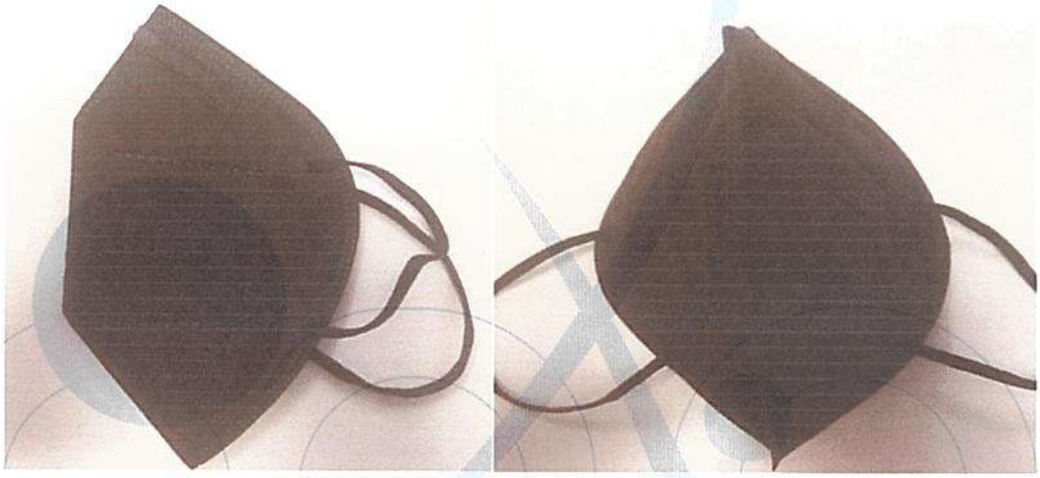
2. **PPE INFORMATION:**
   Disposable and non-sterile half mask made of particulate protection fitler material.

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

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			
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 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 (%)						
	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 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

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)
- User Instruction

CONTROLLER : VOLKAN AKIN

SING :

DATE : 20.04.2021