

AB Tip İnceleme Sertifikası EU Type-Examination Certificate

Belge No / Certificate No : 230-21-01
**Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /
Certification Date / Certificate Validity Date** : 28.04.2021-28.04.2026
Belge Geçerlilik Tarihi / Document Validity Period : 5 yıl / 5 years
**Firma Unvanı ve Adresi /
Company Name and Address** : SU BİYOMEDİKAL SİSTEMLER VE
SAĞLIK HİZMETLERİ SANAYİ VE
TİCARET LİMİTED ŞİRKETİ
Orhangazi Mah. 1673. Sok. No: 20/2-3
Esenyurt / İstanbul
Ürün Adı /Modeller / Product Name / Models : SUBMED / SM001
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-2021-00418
Ürün Tipi / Product Type:
- EN 149:2001+ A1:2009 Solunumla ilgili koruyucu cihazlar - Parçacıklara karşı koruma amaçlı filtreli yarım maskeler/ Respiratory protective devices - Filtering half masks to protect against particles

Ürünün Malzeme Bilgisi / Product Material Information: SUBMED / SM001 model ürünleri kumaş, elastik kayış, burun klipsi, filtre katmanı kullanılarak imal edilmiştir./ SUBMED / SM001 model products are manufactured using fabric, elastic strap, nose clip, filter layer.

Volkan AKIN
28.04.2021
Karar Verici / Approver



Okan AKEL
28.04.2021
Şirket Müdürü / General manager







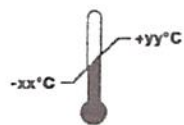

ATTACHMENTS (230-21-01)

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 : SUBMED / SM001

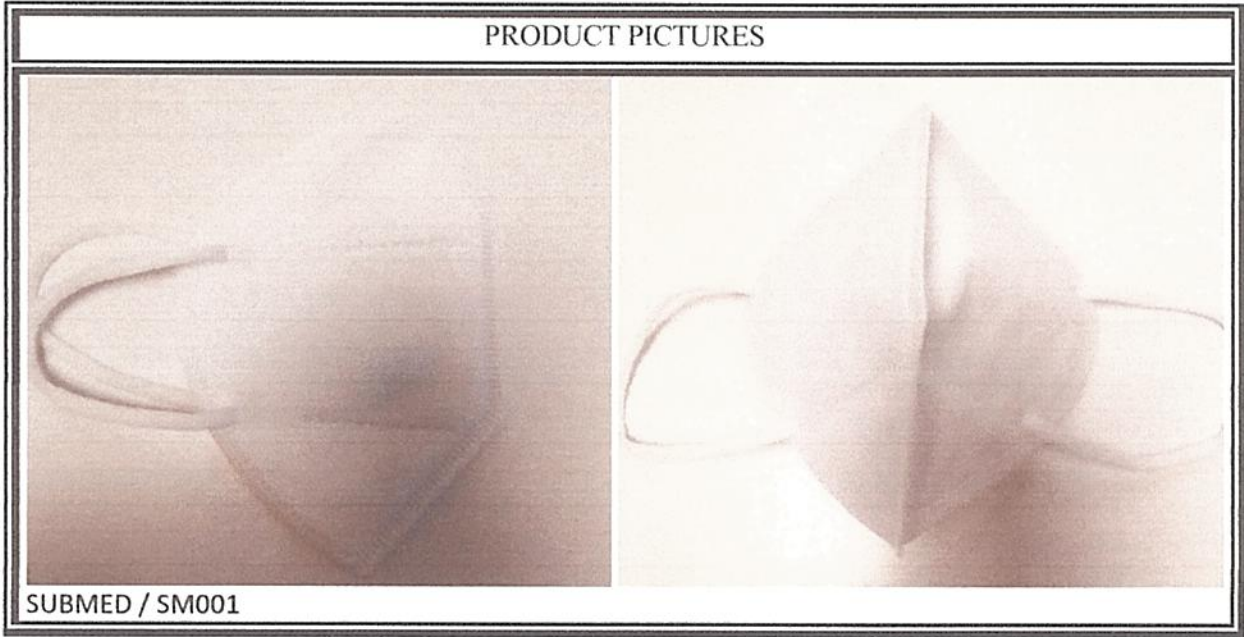
PPE SPECIFICATION	PERFORMANCE LEVELS
Classification	FFP2
Reusable / Single Shift Use	NR

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: SU BİYOMEDİKAL SİSTEMLER VE SAĞLIK HİZMETLERİ SANAYİ VE TİCARET LİMİTED ŞİRKETİ	
PPE TYPE :	
- EN 149:2001+ A1:2009 Respiratory protective devices - Filtering half masks to protect against particles	
MODEL: SUBMED / SM001	
PICTOGRAM AND PERFORMANCE LEVELS:	
EN 149:2001+ A1:2009 FFP2 NR	
 NB 2841	
 Year Month	 yyyy/mm
 -xx°C +yy°C	 < xx%
Or Condition of Storage	

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

ATTACHMENTS (230-21-01)



DOCUMENTS IN THE TECHNICAL FILE

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

Report No : 230-21-01

Report Date : 28.04.2021

Application No : 230-21-01

1. COMPANY INFORMATION:

SU BİYOMEDİKAL SİSTEMLER VE SAĞLIK HİZMETLERİ SANAYİ VE TİCARET LİMİTED ŞİRKETİ
Orhangazi Mah. 1673. Sok. No: 20/2-3 Esenyurt / İstanbul

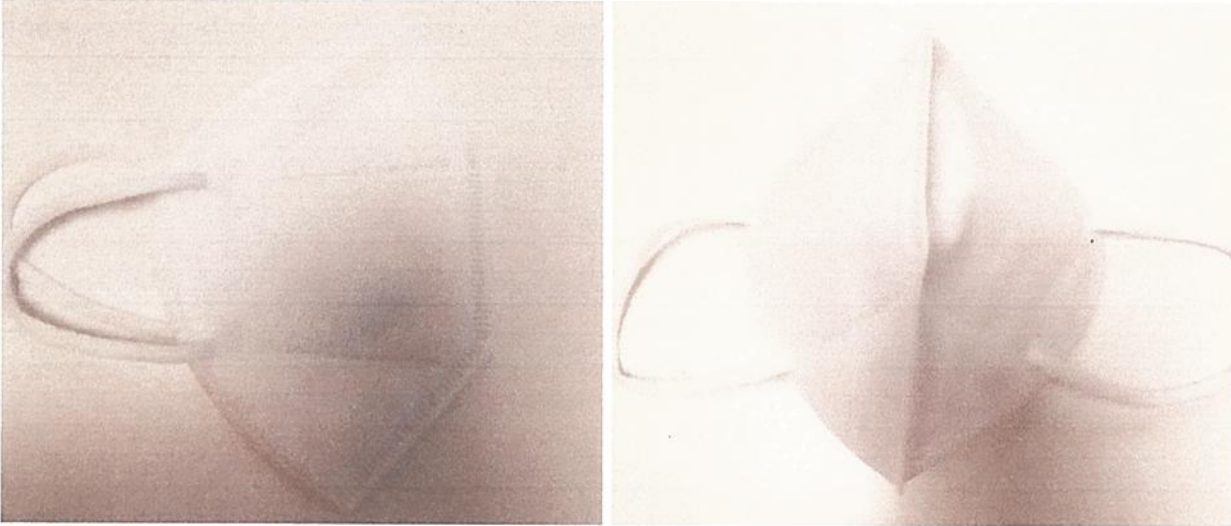
2. PPE INFORMATION:

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



SUBMED / SM001

5. PPE DIMENSIONS:

SUBMED / SM001 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			
Part 7.3 Visual inspection	Shall also the marking and the information supplied by the manufacturer				Appropriate	-	PASS
Banned Azo Dyes	< 30 mg/kg				Not applicable	-	Not applicable
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)	7.4	8.6	8.0	8.5	6.8	7.9
Subject 2 (As recieved)	8.0	5.6	6.1	6.8	6.7	6.6
Subject 3 (As recieved)	7.7	8.9	7.4	8.6	8.0	8.1
Subject 4 (As recieved)	7.6	8.3	8.1	8.6	8.9	8.3
Subject 5 (As recieved)	7.4	8.6	8.0	5.7	7.5	7.4
Subject 6 (After temperature conditioning)	7.7	8.0	6.2	6.8	9.0	7.5
Subject 7 (After temperature conditioning)	7.4	7.4	8.6	8.0	7.5	7.8
Subject 8 (After temperature conditioning)	7.4	8.6	8.0	8.0	7.7	7.9
Subject 9 (After temperature conditioning)	8.6	8.0	6.2	8.5	8.0	7.9
Subject 10 (After temperature conditioning)	6.2	8.5	5.7	7.5	8.5	7.3

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	3.9	4.2
As received	4.2	4.5
As received	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	5.7	5.2
Mechanical strength and temperature conditioning	5.5	5.8
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				0,86 0,80 0,85	-	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
After the flow conditioning	-	-
After the flow conditioning	-	-
After the flow conditioning	-	-

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	2,7	2,8
As recieved	2,7	2,8	2,8	2,7	2,8
As recieved	2,7	2,8	2,8	2,7	2,8
After temperature conditioning	2,7	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	2,7	2,8	2,8
After the simulated wearing treatment	2,8	2,8	2,7	2,8	2,8
After the simulated wearing treatment	2,8	2,8	2,8	2,8	2,8
After the flow conditioning	-	-	-	-	-
After the flow conditioning	-	-	-	-	-
After the flow conditioning	-	-	-	-	-

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 where possible by hand.	Not applicable	-	Not applicable
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9. DECISION

Analysis and examinations SUBMED / SM001 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

CONTROLLER : VOLKAN AKIN

SIGN :

DATE : 28.04.2021

