

AB Tip İnceleme Sertifikası EU Type-Examination Certificate

Belge No / Certificate No : 36-20-01-R03
**Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /
Certification Date / Certificate Validity Date** : 05.01.2021-01.09.2025
Belge Geçerlilik Tarihi / Document Validity Period : 5 yıl / 5 years
**Firma Unvanı ve Adresi /
Company Name and Address** : ORJİN Sağlık Ürünleri Medikal Tekstil Turizm İnşaat
San. Ve Tic. Ltd. Şti.
6118 Sokak No: 9 Egemenlik Mah. Bornova/ İZMİR

Ürün Adı /Modeller / Product Name / Models : ORJİN 1232
Direktifi / Directive : 2016/425 REGULATION
Modülü/Kategori / Module / Category : B MODÜLÜ/ KATEGORİ III
MODULE B / CATEGORY III
Test Rapor No/ları / Test Report No : MNA M-2020-00250

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

Ürünün Malzeme Bilgisi / Product Material Information: ORJİN 1232 model ürünleri kumaş, elastik kayış,
burun klipsi ve filtre katmanı kullanılarak imal edilmiştir./ ORJİN 1232 model products are manufactured using
fabric, elastic strap, nose clip, filter layer.

Revizyon nedeni/ Reason for revision: Model adı revize edilmiştir./ The model name has been revised.

Volkan AKIN
05.01.2021

Karar Verici / Approver



Okan AKEL
05.01.2021

Şirket Müdürü / General manager







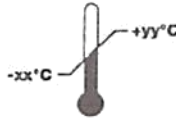

ATTACHMENTS (36-20-01-R03)

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 : ORJİN 1232

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: ORJİN Sağlık Ürünleri Medikal Tekstil Turizm İnşaat San. Ve Tic. Ltd. Şti.	
PPE TYPE :	
- EN 149:2001+ A1:2009 Respiratory protective devices - Filtering half masks to protect against particles	
MODEL: ORJİN 1232	
PICTOGRAM AND PERFORMANCE LEVELS:	
EN 149:2001+ A1:2009 FFP2 NR	
 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.

7. ESSENTIAL HEALTH AND SAFETY REQUIREMENTS

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

8. ANALYSIS AND EVALUATIONS:

EN 149:2001 +A1:2009

TESTS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		FFP1	FFP2	FFP3			
Visual inspection	Shall also the marking and the information supplied by the manufacturer				Appropriate	-	PASS
Total inward leakage	At least 46 out of the 50 individual exercise result	<25	<11	<5	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)	5.1	5.0	4.9	5.1	5.1	5.0
Subject 2 (As recieved)	5.0	5.1	5.1	4.9	5.1	5.0
Subject 3 (As recieved)	5.0	4.9	5.0	5.0	5.1	5.0
Subject 4 (As recieved)	5.0	5.0	5.3	5.1	5.0	5.1
Subject 5 (As recieved)	5.1	5.0	5.0	4.8	4.9	5.0
Subject 6 (After temperature conditioning)	5.0	5.1	5.2	5.1	5.1	5.1
Subject 7 (After temperature conditioning)	5.2	4.9	5.1	5.1	4.9	5.0
Subject 8 (After temperature conditioning)	5.0	5.1	5.1	5.0	5.1	5.1
Subject 9 (After temperature conditioning)	5.0	5.0	5.0	5.1	5.1	5.0
Subject 10 (After temperature conditioning)	5.3	5.1	5.1	5.1	5.1	5.1

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				0,77 0,73 0,75	-	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	4.7	4.4
As recieved	4.3	4.7
As recieved	4.9	4.6
After the simulated wearing treatment	4.8	4.8
After the simulated wearing treatment	5.0	4.6
After the simulated wearing treatment	4.8	4.8
Mechanical strength and temperature conditioning	5.0	4.9
Mechanical strength and temperature conditioning	4.6	4.9
Mechanical strength and temperature conditioning	4.9	4.6

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

Breathing Resistance	Inhalation 30L/min	Inhalation 95L/min
As recieved	0.5	2.1
As recieved	0.4	2.1
As recieved	0.4	2.0

After temperature conditioning	0.4	2.1
After temperature conditioning	0.5	2.0
After temperature conditioning	0.5	2.0
After the simulated wearing treatment	0.5	2.0
After the simulated wearing treatment	0.4	2.1
After the simulated wearing treatment	0.4	2.0

Breathing Resistance 160L/min	Facing directly ahead	Facing vertically upwards	Facing vertically downwards	Lying on the left side	Lying on the right side
As recieved	2,7	2,7	2,7	2,7	2,7
As recieved	2,6	2,7	2,7	2,7	2,7
As recieved	2,7	2,7	2,6	2,6	2,6
After temperature conditioning	2,6	2,6	2,7	2,7	2,7
After temperature conditioning	2,7	2,7	2,7	2,7	2,6
After temperature conditioning	2,7	2,6	2,7	2,7	2,7
After the simulated wearing treatment	2,7	2,7	2,7	2,6	2,6
After the simulated wearing treatment	2,7	2,7	2,7	2,7	2,7
After the simulated wearing treatment	2,7	2,7	2,7	2,7	2,7

9. DECISION PROPOSAL

Analysis and examinations ORJİN 1232 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 revised.

CONTROLLER : VOLKAN AKIN

SING :

DATE : 05.01.2021

