

AB Tip İnceleme Sertifikası EU Type-Examination Certificate

Belge No / Certificate No : 92-20-03-R02
**Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /
Certification Date / Certificate Validity Date** : 12.03.2021-25.12.2025
Belge Geçerlilik Tarihi / Document Validity Period : 5 yıl / 5 years
**Firma Unvanı ve Adresi /
Company Name and Address** : FAGO MEDİKAL SAN. VE TİC. LTD. ŞTİ.
15 Temmuz Mah. Cami Yolu Cad. No:106 / Z1 Bağcılar/
İSTANBUL

Ürün Adı /Modeller / Product Name / Models : FAGO S 101
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-2020-00576, M-2021-00097, M-2021-00383
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: FAGO S 101 model ürünleri kumaş, kulak kayışı, burun klipsi ve filtre katmanı kullanılarak imal edilmiştir./ FAGO S 101 model products are manufactured using fabric, earloop, nose clip and filter layer.

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

Volkan AKIN
12.03.2021

Karar Verici / Approver



Okan AKEL
12.03.2021

Şirket Müdürü / General manager




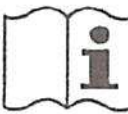
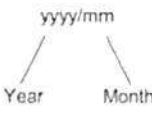

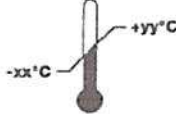

ATTACHMENTS (92-20-03-R02)

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 : FAGO S 101

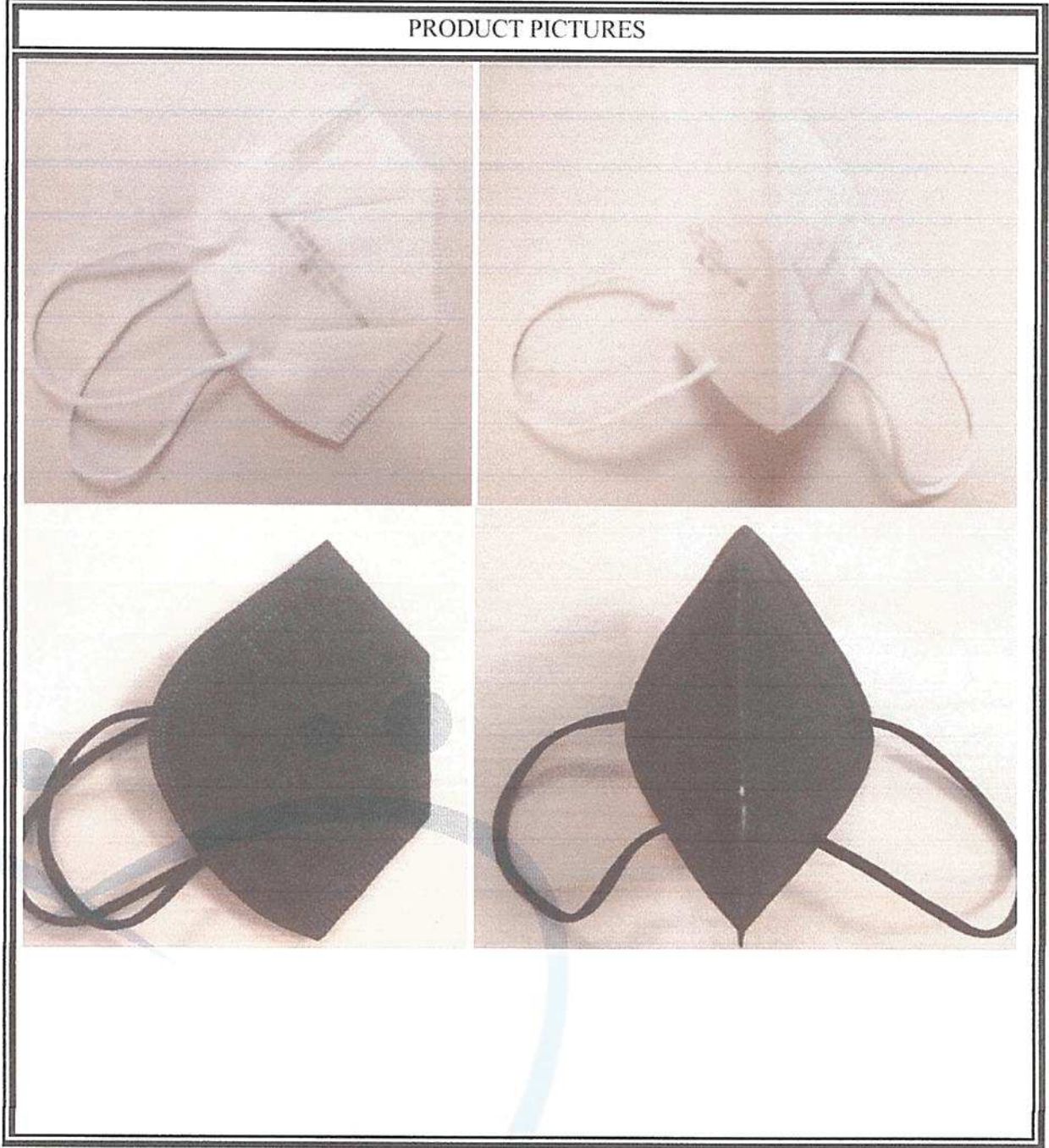
PPE SPECIFICATION	PERFORMANCE LEVELS
Classification	FFP2
Reusable / Single Shift Use	NR

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: FAGO MEDİKAL SAN. VE TİC. LTD. ŞTİ					
PPE TYPE :					
- EN 149:2001+ A1:2009 Respiratory protective devices - Filtering half masks to protect against particles					
MODEL: FAGO S 101					
PICTOGRAM AND PERFORMANCE LEVELS:					
EN 149:2001+ A1:2009 FFP2 NR					
 NB 2841			 yyyy/mm		
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 (92-20-03-R02)



ATTACHMENTS (92-20-03-R02)



DOCUMENTS IN THE TECHNICAL FILE

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

Report No : 92-20-03-R02

Report Date : 12.03.2021

Application No : 92-20-03

1. COMPANY INFORMATION:

FAGO MEDİKAL SAN. VE TİC. LTD. ŞTİ.

15 Temmuz Mah. Cami Yolu Cad. No:106 / Z1 Bağcılar/ İSTANBUL

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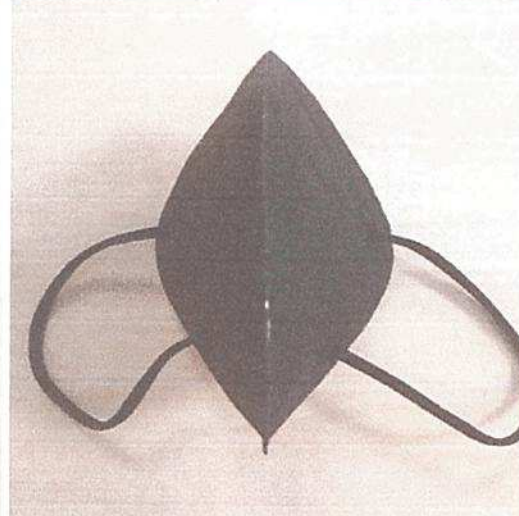
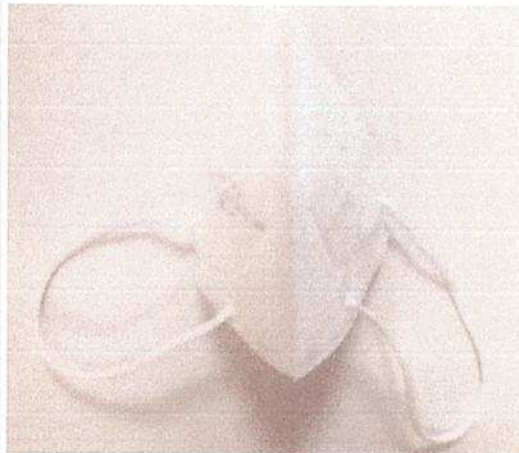
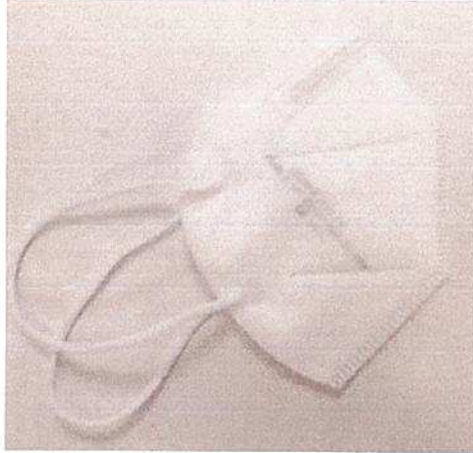
2. PPE INFORMATION:

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





FAGO S 101

5. PPE DIMENSIONS:

FAGO S 101 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, 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.
- 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

WHITE

Total Inward Leakage (%)						
	Exercise 1	Exercise 2	Exercise 3	Exercise 4	Exercise 5	Average
Subject 1 (As recieved)	4.6	4.9	4.8	5.4	4.7	4.9
Subject 2 (As recieved)	5.4	5.3	4.7	4.8	5.5	5.1
Subject 3 (As recieved)	4.9	5.3	4.9	4.9	4.9	5.0
Subject 4 (As recieved)	4.8	4.9	4.8	5.4	5.5	5.1
Subject 5 (As recieved)	5.4	4.7	4.9	5.0	4.9	5.0
Subject 6 (After temperature conditioning)	4.9	4.9	4.8	5.4	4.8	5.0
Subject 7 (After temperature conditioning)	5.5	5.0	5.1	6.0	6.2	5.6
Subject 8 (After temperature conditioning)	5.5	5.2	5.5	4.7	4.7	5.1
Subject 9 (After temperature conditioning)	4.9	4.8	4.9	4.6	4.9	4.8
Subject 10 (After temperature conditioning)	5.0	4.9	4.7	4.8	4.8	4.8

BLACK

Total Inward Leakage (%)						
	Exercise 1	Exercise 2	Exercise 3	Exercise 4	Exercise 5	Average
Subject 1 (As recieved)	2,6	3,5	1,7	3,0	3,1	2,8
Subject 2 (As recieved)	4,4	3,4	2,6	4,6	2,9	3,6
Subject 3 (As recieved)	4,1	1,7	2,2	2,9	2,8	2,7
Subject 4 (As recieved)	3,8	4,9	2,3	4,6	4,7	4,1
Subject 5 (As recieved)	3,7	4,4	4,2	4,7	4,8	4,4
Subject 6 (After temperature conditioning)	3,5	4,7	4,1	1,8	3,6	3,5
Subject 7 (After temperature conditioning)	3,8	4,1	2,3	2,9	5,1	3,6
Subject 8 (After temperature conditioning)	3,8	4,0	3,7	2,7	3,6	3,6
Subject 9 (After temperature conditioning)	3,9	5,1	3,5	3,6	3,8	4,0
Subject 10 (After temperature conditioning)	2,5	4,8	5,0	4,6	5,2	4,4

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				WHITE 0,70 0,75 0,71	BLACK 0,72 0,70 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	

WHITE

Penetration of filter material	Sodium Chloride (%)	Paraffin Oil (%)
As recieved	3.6	2.8
As recieved	3.3	3.2
As recieved	3.5	3.0
After the simulated wearing treatment	3.2	2.9
After the simulated wearing treatment	3.6	2.6
After the simulated wearing treatment	3.6	3.1
Mechanical strength and temperature conditioning	3.4	3.1
Mechanical strength and temperature conditioning	3.0	3.0
Mechanical strength and temperature conditioning	3.5	3.2

BLACK

Penetration of filter material	Sodium Chloride (%)	Paraffin Oil (%)
As recieved	2,8	2,7
As recieved	2,8	2,7
As recieved	2,8	2,7
After the simulated wearing treatment	2,7	2,8
After the simulated wearing treatment	2,7	2,8
After the simulated wearing treatment	2,9	2,9
Mechanical strength and temperature conditioning	3,0	3,0
Mechanical strength and temperature conditioning	3,0	3,0
Mechanical strength and temperature conditioning	3,1	3,0

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

WHITE

Breathing Resistance (mbar)	Inhalation 30L/min (mbar)	Inhalation 95L/min (mbar)
As recieved	0.5	1.9
As recieved	0.5	1.9
As recieved	0.4	1.8
After temperature conditioning	0.4	1.8
After temperature conditioning	0.4	1.9
After temperature conditioning	0.5	1.9
After the simulated wearing treatment	0.4	1.8
After the simulated wearing treatment	0.4	1.9
After the simulated wearing treatment	0.5	1.9

BLACK

Breathing Resistance (mbar)	Inhalation 30L/min (mbar)	Inhalation 95L/min (mbar)
As recieved	0,4	1,7
As recieved	0,4	1,7
As recieved	0,4	1,8
After temperature conditioning	0,4	1,8
After temperature conditioning	0,4	1,8
After temperature conditioning	0,4	1,7
After the simulated wearing treatment	0,5	1,7
After the simulated wearing treatment	0,5	1,7
After the simulated wearing treatment	0,5	1,7

WHITE

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	2,0	2,0	2,0	2,0	2,0
As recieved	1,9	2,0	2,0	2,0	2,0
As recieved	2,0	2,0	2,0	2,0	2,0
After temperature conditioning	1,9	2,0	1,9	2,0	2,0
After temperature conditioning	1,9	2,0	2,0	1,9	2,0
After temperature conditioning	1,9	2,0	2,0	2,0	2,0
After the simulated wearing treatment	1,9	1,9	1,9	2,0	2,0

After the simulated wearing treatment	2,0	2,0	1,9	1,9	1,9
After the simulated wearing treatment	2,0	2,0	2,0	2,0	2,0

BLACK

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	1,8	1,8	1,8	1,8	1,9
As recieved	1,8	1,8	1,8	1,8	1,8
As recieved	1,8	1,8	1,8	1,8	1,8
After temperature conditioning	1,8	1,9	1,8	1,8	1,8
After temperature conditioning	1,8	1,9	1,8	1,8	1,8
After temperature conditioning	1,8	1,9	1,8	1,8	1,8
After the simulated wearing treatment	1,8	1,8	1,8	1,8	1,8
After the simulated wearing treatment	1,8	1,8	1,8	1,9	1,9
After the simulated wearing treatment	1,8	1,8	1,8	1,9	1,8

9. DECISION PROPOSAL

Analysis and examinations FAGO S 101 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 : Different color products have been added.

CONTROLLER : VOLKAN AKIN

SING :

DATE : 12.03.2021

