

EU DECLARATION OF CONFORMITY

MANUFACTURER

FAGO MEDİKAL SANAYİ VE TİCARET LİMİTED ŞİRKETİ

15 Temmuz Mahallesi Cami Yolu Caddesi No:106 İç Kapı No: Z1 Bağcılar İSTANBUL /
TURKEY

PRODUCT DESCRIPTION

Brand Name: Fago **Model:** FAGO S 101

Filtering Half Mask

Class: FFP2 NR

Particle Filtering Half Face Mask in Category III product according to (EU) 2016/425 Personal Protective Equipment Regulation

The Manufacturer declares on his sole responsibility that the product above is, under conditions of normal use and conditions defined by the Manufacturer, safe and meets all the necessary legal conditions and requirements. The product is a personal protective equipment that is intended for single use and solely in accordance with the Manufacturer's instructions.

The Conformity is ensured with the following mechanism:

- Complies with EU 2016/425 Personal Protective Equipment Regulation establishing technical requirements for Category III products,
- Complies with Essential Health and Safety Requirements of Technical harmonised standard EN 149:2001 +A1:2009
- All required tests referred in above standards are conducted,
- Complies with other relevant harmonized legislation and community standards
- For the assessment of conformity the EU Type Examination certificate (Serial No:92-20-03) is issued, after all technical evaluations for conformity to the regulation and harmonised standards conducted, by;
 - MNA LAB SAN TIC LTD STI, as Notified Body number 2841
- The product is under surveillance of same Notified Body, NB 2841 according to the Annex III (Module C2) of the PPE Regulation (EU) 2016/425, for quality assurance.

MARKING, LABELLING

Marking, labelling and user information are prepared in accordance with EU 2016/425 Personal Protective Equipment Regulation and the harmonised product standards given above.

MEASURES TO ENSURE CONFORMITY

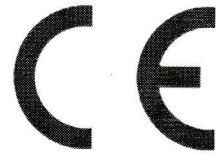
The Manufacturer declares that he has taken all necessary measures to ensure the conformity of products placed on the market with technical documentation and technical requirements for this type of product.

GÖKHAN AYDIN

General Manager

25/12/2020

FAGO MEDİKAL SAN. VE TİC. LTD. ŞTİ.
15 Temmuz Mh. Cami Yolu Cd. No:106/Z1
Bağcılar/İST. Tic. Sic. No: 240684-S
Güncel V.D.: 3840738071
Mersis No: 0384073807100001



2841

**CONFORMITY TO TYPE BASED ON INTERNAL
PRODUCTION CONTROL PLUS SUPERVISED PRODUCT
CHECK AT RANDOM INTERVALS
(MODULE C2, ANNEX VII) (92-20-03-01)**

Report No : 92-20-03-01

Report Date : 12.01.2021

Application No : 92-20-03-01

1. COMPANY INFORMATION:

FAGO MEDİKAL SAN. VE TİC. LTD. ŞTİ.

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

Tel: +90 532 388 44 44

E-mail: burak@unionmedikal.com

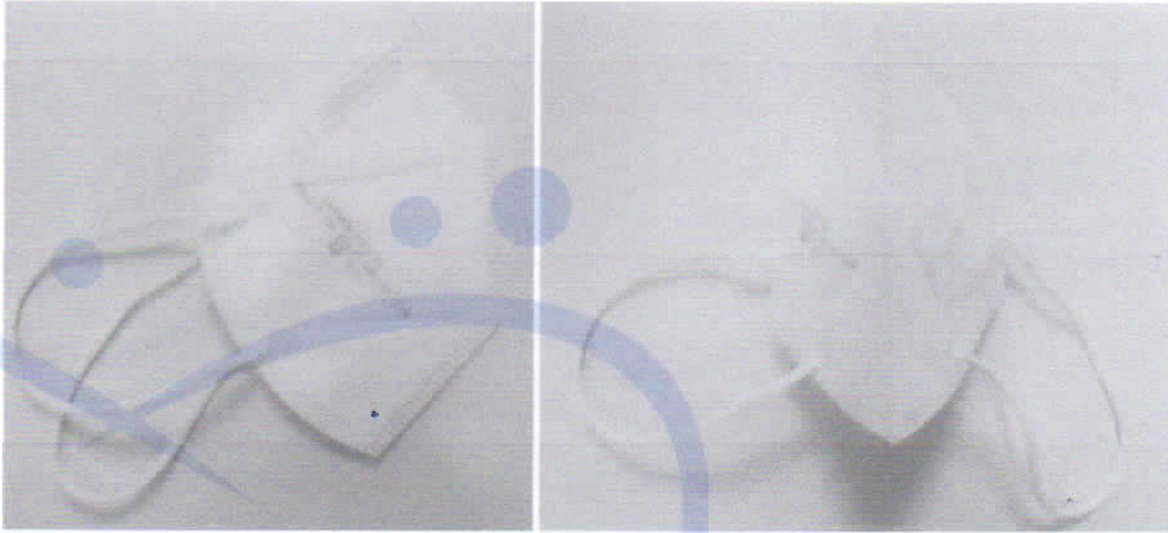
2. PPE INFORMATION:

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



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 mask is made of elastic strap, nonwoven fabric on the outer and inner layers and filter material on the middle layer.

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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)	4.9	5.2	5.1	5.7	5.0	5.2
Subject 2 (As recieved)	5.7	5.6	5.0	5.1	5.8	5.4
Subject 3 (As recieved)	5.2	5.6	5.2	5.2	5.2	5.3
Subject 4 (As recieved)	5.1	5.2	5.1	5.7	5.8	5.4
Subject 5 (As recieved)	5.7	5.0	5.2	5.3	5.2	5.3
Subject 6 (After temperature conditioning)	5.2	5.2	5.1	5.7	5.1	5.3
Subject 7 (After temperature conditioning)	5.8	5.3	5.4	6.3	6.5	5.9
Subject 8 (After temperature conditioning)	5.8	5.5	5.8	5.0	5.0	5.4
Subject 9 (After temperature conditioning)	5.2	5.1	5.2	4.9	5.2	5.1
Subject 10 (After temperature conditioning)	5.3	5.2	5.0	5.1	5.1	5.1

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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 0.76	-	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	3.2	3.3
As recieved	3.3	3.1
As recieved	3.1	3.2
After the simulated wearing treatment	3.6	2.7
After the simulated wearing treatment	3.8	3.4
After the simulated wearing treatment	3.8	3.5
Mechanical strength and temperature conditioning	3.4	3.6
Mechanical strength and temperature conditioning	3.5	3.1
Mechanical strength and temperature conditioning	3.4	3.6

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 (mbar)	Inhalation 30L/min	Inhalation 95L/min
As recieved	0.3	1.7
As recieved	0.3	1.7
As recieved	0.4	1.7

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After temperature conditioning	0.4	1.8
After temperature conditioning	0.3	1.8
After temperature conditioning	0.4	1.8
After the simulated wearing treatment	0.3	1.7
After the simulated wearing treatment	0.4	1.8
After the simulated wearing treatment	0.4	1.8

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

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. 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
- User Instruction

CONTROLLER : VOLKAN AKIN

SING :

DATE : 12.01.2021



AB Tip İnceleme Sertifikası EU Type-Examination Certificate

Belge No / Certificate No : 92-20-04
Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /
Certification Date / Certificate Validity Date : 15.01.2021-15.01.2026
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 104
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-2020-00577

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: FAGO 104 model ürünleri kumaş, kulak kayışı, burun klipsi ve filtre katmanı kullanılarak imal edilmiştir./ FAGO 104 model products are manufactured using fabric, earloop, nose clip and filter layer.

Volkan AKIN

15.01.2021

Karar Verici / Approver

Okan AKEL

15.01.2021

Şirket Müdürü / General manager

