EU DECLARATION OF CONFORMITY

MANUFACTURER
FAGO MEDİKAL SANAYİ VE TİCARET LİMİTED ŞİRKETİ
15 Temmuz Mahallesi Cami Yolu Caddesi No:106 Iç Kapı No: Z1 Bağcılar ISTANBUL / 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 accrding 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 Personel 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/IST. Tic. Sic. No: 249684-5
Gümrük V.D.: 384 073 8071
Mersis No: 0384 0738 0710 0001

CE
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Digitally signed by Palii Nina
Date: 2022.10.06 11:03:45 EEST
Reason: MoldSign Signature
Location: Moldova

CERTIFICATE
of Registration

CERTIFIED STAUNCHLY MANAGEMENT SYSTEM

This is to Certify that the

Medical Devices – Quality Management System

of

FAGO MEDİKAL SANAYİ VE TİCARET LİMİTED ŞİRKETİ

15 TEMMUZ MAH. CAMİ YOLU CAD. NO:106/Z1 BAĞCILAR / İSTANBUL / TÜRKİYE

has been independently assessed and is compliant with the requirements of

ISO 13485:2016

This Certificate is applicable to the following product or service ranges:

MANUFACTURE AND SALES OF MEDICAL MASK, FFP3 / FFP2 / N 95 MASK, 3-LAYER LAYERED PROTECTIVE FACE MASK, PERSONAL PROTECTIVE MASK, MEDICAL OVERALLS, PERSONAL PROTECTIVE OVERALLS, PROTECTIVE FACE MASK, FACE SHIELD, GOWNS, DISPOSABLE GOWNS, SURGICAL GOWNS, PATIENT AND VISITOR GOWNS, OVERSHOES, BONNET, GLOVES, PATIENT BED SHEET, MEDICAL BRIEFS, EXAMINATION AND SURGICAL COVER, SURGICAL GOWN, DOCTOR AND MEDICAL STAFF GOWN

TIBBİ MASKE, FFP3 / FFP2 / N 95 MASKE, 3 KATLI KATMANLI KORUYUCU YÜZ MASKESİ, KİŞİSEL KORUYUCU MASKE, TIBBİ TULUM, KİŞİSEL KORUYUCU TULUM, KORUYUCU YÜZ MASKESİ, YÜZ SİPERİ, ÖNLÜK, TEK KULLANIMLIK ÖNLÜK, CERRAHİ ÖNLÜK, HASTA VE ZİYARETÇİ ÖNLÜĞÜ, GALOŞ, BONE, ELDİVEN, HASTA ÇARŞAFI, MEDİKAL KÜLOT, MUAYENE VE AMELİYAT ÖRTÜSÜ, AMELİYAT ÖNLÜĞÜ, DOKTOR VE SAĞLIK PERSONELİ ÖNLÜĞÜ ÜRETİMİ VE SATIŞI

:: Certificate No :: TR5288111

Date of initial registration	**20 July 2020**
Date of this Certificate	**20 July 2020**
Surveillance audit on or before	**19 July 2021**
Recertification Due / Certificate expiry	**19 July 2023**

IAS IAF

Director

STAUNCHLY MANAGEMENT & SYSTEM SERVICES LTD.
Suite 45, 88-90 Hatton Garden, London, EC1N 8PN.
Phone : +44 345 520 0105
Email : info@staunchyservices.com Web : www.staunchyservices.com

MNA LABORATUVARLARI
Notified Body Number: 2841

AB Tip İnceleme Sertifikası
EU Type-Examination Certificate

Belge No / *Certificate No*	: 92-20-03
Belgelendirme Tarihi - Bir Sonraki Belge Tarihi / *Certification Date / Certificate Validity Date*	: 25.12.2020-25.12.2025
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

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 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.*

Volkan AKIN	***Okan AKEL***
25.12.2020	***25.12.2020***
Karar Verici / Approver	***Şirket Müdürü / General manager***

Notified Body Number: 2841

ATTACHMENTS (92-20-03)

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

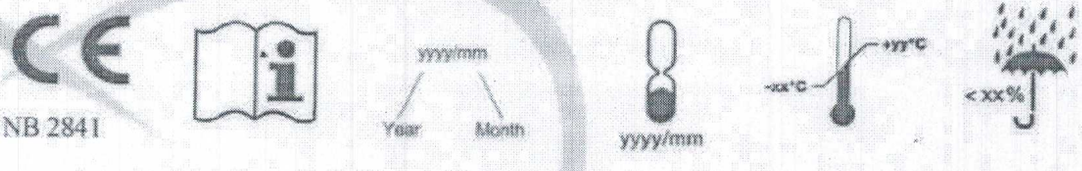
PPE TYPE :

- 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

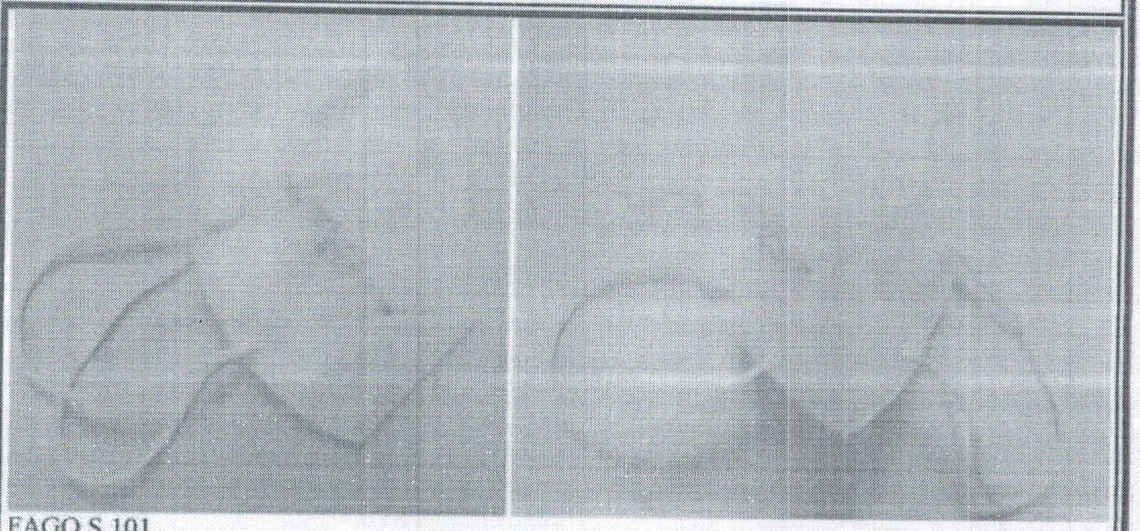


Or Condition of Storage

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.

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

ATTACHMENTS (92-20-03)

PRODUCT PICTURES

FAGO S 101

DOCUMENTS IN THE TECHNICAL
- Basic Health Safety Requirements - Risk Assessment - Test Reports - Technical Report

MNA LABORATUVARLARI SAN. TİC. LTD. ŞTİ.	MNA LABORATUVARLARI
	TECHNICAL EVALUATION REPORT (92-20-03)

Report No : 92-20-03

Report Date : 25.12.2020

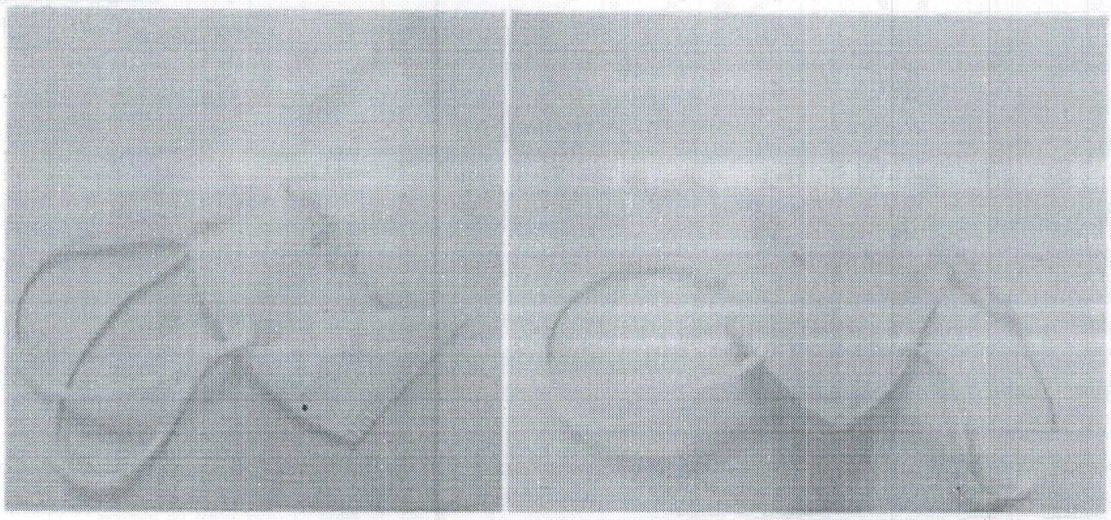
Application No : 92-20-03

1. **COMPANY INFORMATION:**
   FAGO MEDİKAL SAN. VE TİC. LTD. ŞTİ.
   15 Temmuz Mah. Cami Yolu Cad. No:106 / Z1 Bağcılar/ İSTANBUL
   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 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
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)	4.6	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

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				0,70 0,75 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

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

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 (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
After the flow conditioning	0.9	2.3
After the flow conditioning	0.9	2.4
After the flow conditioning	0.9	2.4

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

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

CONTROLLER : VOLKAN AKIN

SING :

DATE : 25.12.2020