MONDO MEDICAL

FFP2 NR

Mondo Medical GmbH Wittenberger Str.36 041290 / Leipzig – Deutschland
E-Mail : info@mondomedical.eu - Tel:+49 171 2224414
www.mondomedical.eu

MNA LABORATUVARLARI
Notified Body Number: 2841

AB Tip İnceleme Sertifikası
EU Type-Examination Certificate

Belge No / ***Certificate No*** : 188-21-01
Belgelendirme Tarihi - Bir Sonraki Belge Tarihi /
Certification Date / Certificate Validity Date : 17.03.2021-17.03.2026
Belge Geçerlilik Tarihi / ***Document Validity Period*****:** 5 yıl / *5 years*
Firma Unvanı ve Adresi /
Company Name and Address :MONDO MEDİKAL DIŞ TİCARET LİMİTED ŞİRKETİ
Abdurrahman Nafiz Gürman Mah. Turunçlu Sk. Mesa Plaza Apt. No: 25/2 Güngören-İSTANBUL

Ürün Adı /Modeller / ***Product Name / Models*** : M001
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-2021-00273
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*****:** M001 model ürünleri kumaş, elatik kayışı, burun klipsi, filtre katmanı kullanılarak imal edilmiştir./ *M001 model products are manufactured using fabric, elastic strap, nose clip, filter layer.*

Volkan AKIN
17.03.2021
Karar Verici / Approver

Okan AKEL
17.03.2021
Şirket Müdürü / General manager

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

Notified Body Number: 2841

ATTACHMENTS (188-21-01)

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 : M001

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: MONDO MEDİKAL DIŞ TİCARET LİMİTED ŞİRKETİ

PPE TYPE :

- EN 149:2001+ A1:2009 Respiratory protective devices - Filtering half masks to protect against particles

MODEL: M001

PICTOGRAM AND PERFORMANCE LEVELS:

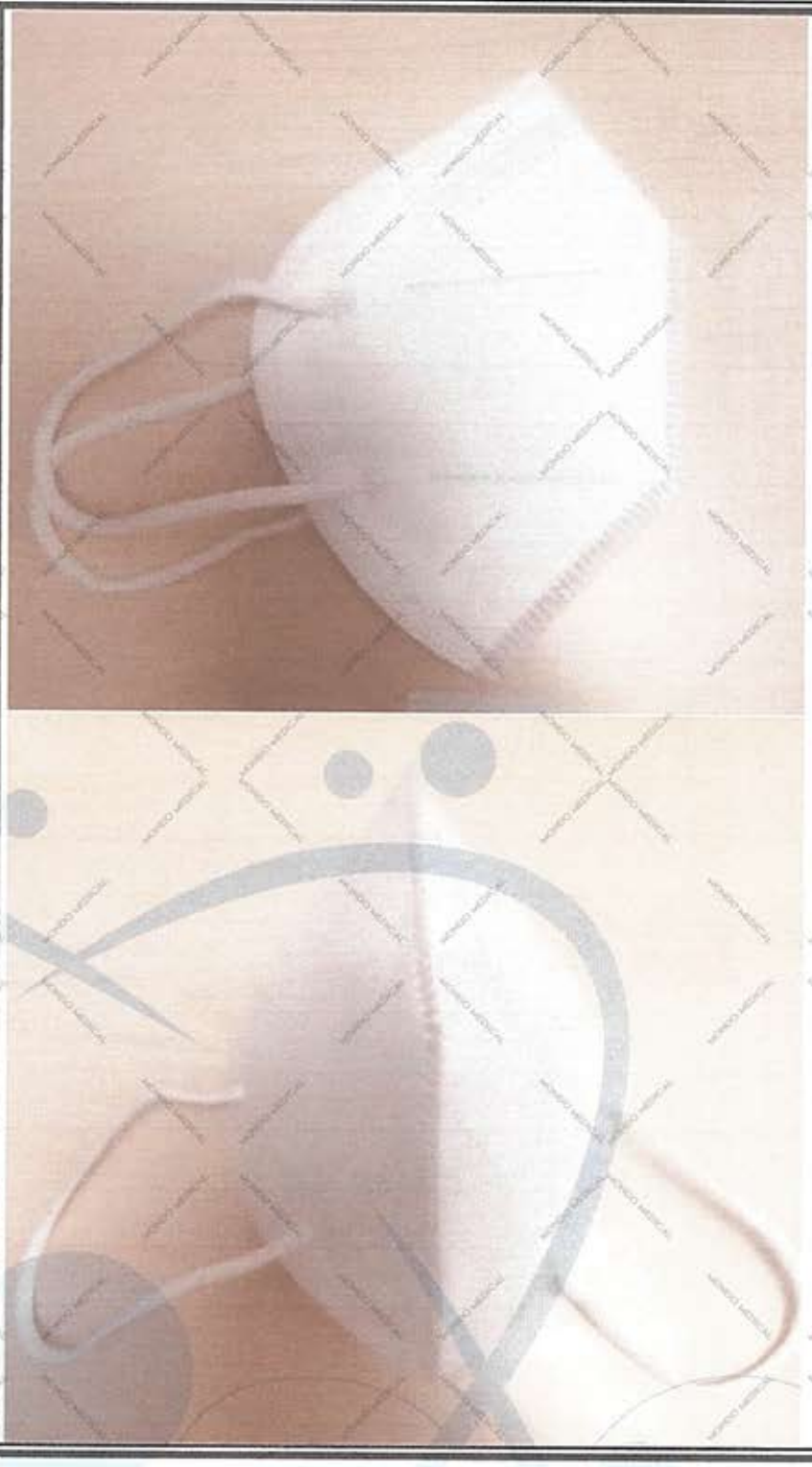
EN 149:2001+ A1:2009 FFP2 NR

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.

ATTACHMENTS (188-21-01)

PRODUCT PICTURES



ATTACHMENTS (188-21-01)

M001

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

Report No : 188-21-01

Report Date :17.03.2021

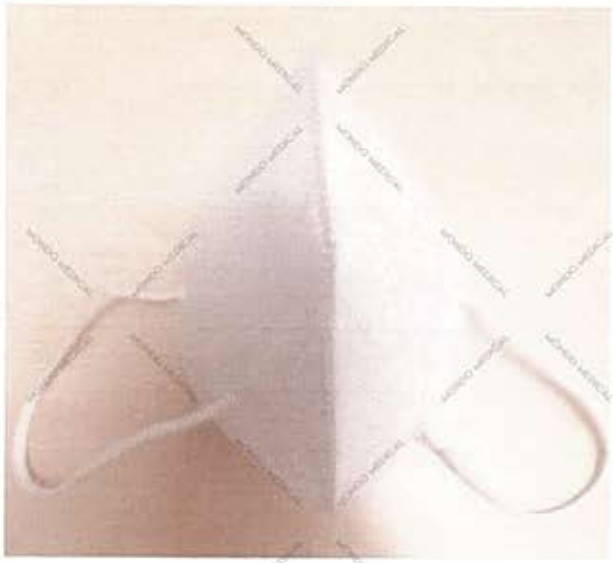
Application No : 188-21-01

1. **COMPANY INFORMATION:**
   MONDO MEDİKAL DIŞ TİCARET LİMİTED ŞİRKETİ
   Abdurrahman Nafiz Gürman Mah. Turunçlu Sk. Mesa Plaza Apt. No: 25/2 Güngören- İSTANBUL
   Tel: 0212 643 83 73
   Mail:info@mondomedical.eu

2. **PPE INFORMATION:**
   Disposable and non-sterile half mask made of particulate protection fitler 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**



M001

5. **PPE DIMENSIONS:**
M001 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 fitler 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
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	After cleaning and disinfecting the re-usable				Not applicable	-	Not applicable

Cleaning and disinfecting	particle filtering half mask shall satisfy the penetration requirement of the relevant class.			
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
Banned Azo Dyes	< 30 mg/kg	< 5 mg/kg	< 30 mg/kg	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)	8,5	7,5	6,7	8,7	7,0	7,7
Subject 2 (As recieved)	8,2	5,8	6,3	7,0	6,9	6,8
Subject 3 (As recieved)	7,9	4,8	6,4	8,7	8,0	7,2
Subject 4 (As recieved)	7,8	8,5	8,3	8,8	8,7	8,4
Subject 5 (As recieved)	7,6	6,8	8,2	5,9	7,7	7,2
Subject 6 (After temperature conditioning)	7,9	8,2	6,4	7,0	6,9	7,3
Subject 7 (After temperature conditioning)	7,9	8,1	7,8	6,8	7,7	7,7
Subject 8 (After temperature conditioning)	8,0	3,3	7,6	7,7	7,9	6,9
Subject 9 (After temperature conditioning)	6,6	5,8	5,3	8,7	5,7	6,4
Subject 10 (After temperature conditioning)	5,5	5,6	5,9	5,8	5,5	5,7

Subject facial dimensions

Subject	Face Length (mm)	Face Width (mm)	Face Depth (mm)	Mouth Width (mm)
1	133	132	132	65
2	125	144	116	67
3	126	135	124	75
4	123	133	134	74
5	117	135	122	73
6	122	142	133	66
7	113	132	114	75
8	135	123	123	65
9	122	135	133	74
10	135	142	125	83

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 recieved	3,5	3,7
As recieved	3,6	3,7
As recieved	3,7	3,8
After the simulated wearing treatment	3,7	3,9
After the simulated wearing treatment	3,8	3,8
After the simulated wearing treatment	3,9	4,0
Mechanical strength and temperature conditioning	5,1	5,4
Mechanical strength and temperature conditioning	5,0	5,2
Mechanical strength and temperature conditioning	5,0	5,2

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				0,81 0,81 0,80	-	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	2,1
As recieved	0.5	2,0
As recieved	0.6	2,0
After temperature conditioning	0.6	2,1
After temperature conditioning	0.6	2,0
After temperature conditioning	0.5	2,0
After the simulated wearing treatment	0.5	2,0
After the simulated wearing treatment	0.6	2,0
After the simulated wearing treatment	0.5	2,0

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	2,6	2,6	2,6	2,6	2,6
As recieved	2,7	2,6	2,7	2,7	2,
As recieved	2,6	2,6	2,6	2,6	2,7
After temperature conditioning	2,6	2,6	2,5	2,6	2,6
After temperature conditioning	2,6	2,6	2,6	2,6	2,6
After temperature conditioning	2,6	2,6	2,6	2,6	2,6
After the simulated wearing treatment	2,6	2,6	2,6	2,6	2,6
After the simulated wearing treatment	2,7	2,6	2,6	2,7	2,6
After the simulated wearing treatment	2,6	2,6	2,6	2,7	2,6

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	3 mbar	4 mbar	5 mbar	Not applicable	-	Not applicable

	not exceed. (valveless)						
Part 7.18 Demountable part	All demountable parts (if fitted) shall be readily connected and secured were possible by hand.				Not applicable	-	Not applicable

9. DECISION

Analysis and examinations M001 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 : **17.03.2021**

EU DECLARATION OF CONFORMITY

MANUFACTURER
MONDO MEDICAL DIS TICARET
ABDURRAHMAN NAFIZ GURMAN MAH.TURUNCLU SOK.MESA PLAZA NO:25 IC KAPI NO:2 / GUNGOREN / ISTANBUL
TURKEY

PRODUCT DESCRIPTION
Brand Name: MONDO **Model:** M001
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.

TANER ÇELİK
General Manager
17/03/2021

MONDO MEDİKAL
DIŞ TİCARET LİMİTED ŞİRKETİ
Abdurrahman Nafiz Gürman Mh. Turunçlu Sokak
Masa Plaza No.25/2 Güngören / İSTANBUL
Mersis V.D. 622 180 5818

CE
2841


MONDO
SCHUTZMASKE
PROTECTIVE MASK
5X
1 STCK PCS
10 STCK PCS
WHITE
WEIß
SOFT
ELASTIC EARS
ANTI ODOR CLOTH
FFP2 NR
EN149:2001+A1:2009
≥95% FILTRATION EFFICIENCY
FILTERLEISTUNG
PARTICLE FILTERING HALF MASK
PARTIKELFILTRIERENDE HALBMASKE
PREMIUM QUALITY PRODUCT
MONDO MEDICAL


MONDO MEDICAL
SCHUTZMASKE
PROTECTIVE MASK
5X
1 STCK PCS
10 STCK PCS
BLACK
SCHWARZ
SOFT
ELASTIC EARS
ANTI ODOR CLOTH
MONDO MEDICAL
M001 FFP2
EN149:2001+A1:2009
CE 2841
FFP2 NR
EN149:2001+A1:2009
≥95%
FILTRATION
EFFICIENCY
FILTERLEISTUNG
PARTICLE FILTERING
HALF MASK
PARTIKELFILTRIERENDE
HALBMASKE
PREMIUM
QUALITY
PRODUCT
MONDO MEDICAL