

AB Tip İnceleme Sertifikası EU Type-Examination Certificate

Belge No / C'criij?cøfr No : 169-21 -01
Belgelendirme Tarihi - Bir Sonrakı Belge Tarihi /
Cenlficatlon Date7 Cenifcate Validty öat• : 25.02.2021-25.02.2026
Belge Geçerlilik Tarihi / Document Validity Period • 5 yıl / 5 years
Firma Unvani ve Adresi /
Company Name ond Address : MEHMET AU TANRI VERDİ YÖRE
MEDICAL
Medis Matt. Kaşğorlı sok. No:11 AB
SANCAKTEPE/İSTANBUL

Ürön Adi fModeller 1 Product Name7 Models : YM-002
Direktifi / Dlrrective : 2016/425 REGULATION
Modülfl/Kategori l Module 7 Category : B MODÜLÜ/ KATEGORİ III
MODULE B / CATEGORY III
Test Rapor Noham / test RepoH No : MNA M-2021-00217
Ürün Tipi / Product type:

- EN 149+ A1 Solunumla ilgili koruyucu cihazlar - Parçacıklara karşı koruma amaçlı filtreli yarım maskeler/ Respiratory protective devices - Filtering half tiiasLs to protect against fparticles

Urüntln Malzeme Bilgisi f Product Material information: YM-002 model tlinleri kumaş, elastik kayış, burun klipsi ve filtrc katmanı kullanılarak imal edilmiştir./ YM-002 tnel products are nianifmactured using fobric, elastic strap, nose cliği. filter layer.

Volkan AKIN
25.02.2021
Karar Verici / Approver

Okan AKEL
25.02.2021
Şirket Müdürü / General manager





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Notified Body Number: 2841

ATTACHMENTS (169-22-01)

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 : YM-002

PPE SPECIFICATION	E O C E L E E S
Classification	P2
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:

MANUFACTURER: MEHMET AU TANRIVERDI YORE MEDICAL

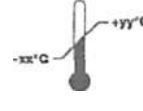
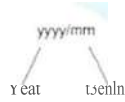
PPE TYPE

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

MODEL: YM-002

PICTOGRAM AND PERFORMANCE LEVELS:

EN 149 A1 FFP2 NR



Or CONDITION of Storage

MNA LABORATORIES SAN. TIC. LTD. Şti declares that the above-mentioned product meets the requirements of the directive according to the EU Directive 2016/425, the safety of the produce 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 1331 www.mnalab.com

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Notified Body Number: 2841

ATTACHMENTS (169-21-01)

PRODUCT PICTURES



YM-002

DOCUMENTS IN THE TECHNICAL FILE

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

MNA Laboratuvarları San. Tic.Ltd .Şti
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U rorm-002/Rev.0</12.03.2020

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	TECHNICAL EVALUATION REPORT (169-21-01)

Report No : 169-21-01

Report Date : 25.02.2021

Application No : 169-21-01

1. COMPANY INFORMATION:

MEHMET ALİ TANRIVERDİ YÖRE MEDİKAL

Meclis Mah. Kaşgarlı sok. No:11 -AB SANCASTEPE/İSTANBUL

Tel: 0216 620 95 18

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



5. PPE DIMENSIONS:

YM-002 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 and 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.

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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	Shaft 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 Cleaning and disinfecting	After cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant class.				Not applicable		Not applicable
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

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 received)	8,7	7,7	6,9	8,9	7,2	7,9
Subject 2 (As received)	8,4	6,0	6,5	7,2	7,1	7,0
Subject 3 (As received)	8,1	9,3	6,6	8,9	9,3	8,4
Subject 4 (As received)	8,0	8,7	8,5	9,0	9,3	8,7
Subject 5 (As received)	7,8	9,0	8,4	6,1	7,9	7,8
Subject 6 (After temperature conditioning)	8,1	8,4	6,6	7,2	9,4	7,9
Subject 7 (After temperature conditioning)	8,1	8,3	8,0	7,0	7,9	7,9
Subject 8 (After temperature conditioning)	8,2	9,3	7,8	7,9	8,1	8,3
Subject 9 (After temperature conditioning)	6,8	9,3	9,3	8,9	9,5	8,8
Subject 10 (After temperature conditioning)	5,2	5,2	5,2	6,2	5,2	5,4

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	TECHNICAL EVALUATION REPORT (169-21-01)

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	P« 20	'X» 6	% 1	See the table below	FFP2	PASS
	Paraffin oil, 95 L/min '«, max	P« 20	'X 6	'« 1	See the table below	FFP2	PASS

Penetration of filter material	Sodium Chloride (9ç)	ParaMn Oil (%)
As recieved	4,0	4,3
As recieved	4,2	4,5
As recieved	4,2	4,4
After the simulated wearing treatment	4,6	4,6
After the simulated wearing treatment	4,1	4,6
After the simulated wearing treatment	4,2	4,5
Mechanical strength and temperature conditioning	5,3	5,5
Mechanical strength and temperature conditioning	5,2	5,3
Mechanical strength and temperature conditioning	5,3	5,5

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 P< 1				0,81 0,84 0,79		PASS
Part 7.13 Head harness	It can be donned and removed easily				Appropriate		PASS

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	TECHNICAL EVALUATION REPORT (169-21-01)

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 aher 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 9SL/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	2,2
AS recieved	0,6	2,2
As recieved	0,6	2,3
After temperature conditioning	0,5	2,3
After temperature conditioning	0,6	2,3
After temperature conditioning	0,6	2,2
After the simulated wearing treatment	0,5	2,3
After the simulated wearing treatment	0,6	2,3
After the simulated wearing treatment	0,6	2,3

Breathing Resistance 160L/mIn (mbar)	Facing directly ahead	Fadng vertically upwards	racing vertically downwards	Lying on the left side	Lying on the right side
As recieved	2,8	2,8	2,8	2,9	2,8
As recieved	2,9	2,8	2,8	2,9	2,8
As recieved	2,9	2,8	2,8	2,9	2,8
After temperature conditioning	2,9	2,8	2,8	2,8	2,8
After temperature conditioning	2,8	2,8	2,8	2,8	2,8
After temperature conditioning	2,8	2,8	2,8	2,8	2,8
After the simulated wearing treatment	2,8	2,8	2,9	2,8	2,8
After the simulated wearing treatment	2,8	2,8	2,9	2,8	2,8
After the simulated wearing treatment	2,8	2,8	2,8	2,8	2,8

TESİS	PARAMETER	PERFORMANCE LEVELS			RESULTS	PERFORMANCE LEVELS	EVALUATION
		4	5	7			
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 t/ min continuous flow. (valved)				Not applicable		Not applicable
	After clogging the inhalation and exhalation resistances shall not exceed. (valveless)	3 mbar	4 mbar	5 mbar	Not applicable		Not applicable
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 PROPOSAL

Analysis and examinations YM-002 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 AXIN

SİGİ

DATE : 25.02.2021