

Report No : 44-20-01-R01-01

Report Date : 25.12.2020

Application No : 44-20-01-01

1. COMPANY INFORMATION:

SÖZDEM TEKSTİL TURİZM TARIM İNŞ. SAN. TİC. LTD. ŞTİ.

Örmegöze Köyü, Organize Sanayi Bölgesi Mevkii 1. Cad. Maksan Grup Apt. No: 30 Beşiri/ BATMAN

Tel: +90 488 502 90 90

E-mail: sozdemtekstil@hotmail.com

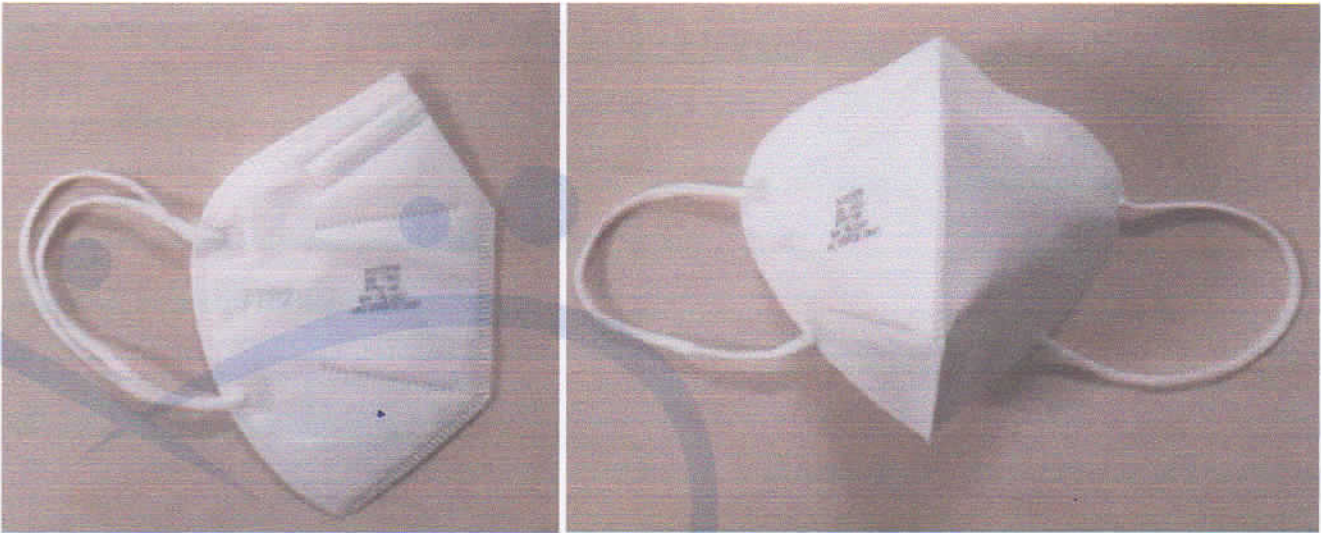
2. PPE INFORMATION:

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



SO 1553

5. PPE DIMENSIONS:

SO 1553 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.

**CONFORMITY TO TYPE BASED ON INTERNAL
PRODUCTION CONTROL PLUS SUPERVISED PRODUCT
CHECK AT RANDOM INTERVALS
(MODULE C2, ANNEX VII) (44-20-01-R01-01)**

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)	5.2	5.5	5.4	6.0	5.3	5.5
Subject 2 (As recieved)	6.0	5.9	5.3	5.4	6.1	5.7
Subject 3 (As recieved)	5.5	5.9	5.5	5.5	5.5	5.6
Subject 4 (As recieved)	5.4	5.5	5.4	6.0	6.1	5.7
Subject 5 (As recieved)	6.0	5.3	5.5	5.6	5.5	5.6
Subject 6 (After temperature conditioning)	5.5	5.5	5.4	6.0	5.4	5.6
Subject 7 (After temperature conditioning)	6.1	5.6	5.7	6.6	6.8	6.2
Subject 8 (After temperature conditioning)	6.1	5.8	6.1	5.3	5.3	5.7
Subject 9 (After temperature conditioning)	5.5	5.4	5.5	5.2	5.5	5.4
Subject 10 (After temperature conditioning)	5.6	5.5	5.3	5.4	5.4	5.4

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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				0.60 0.67 0.63	-	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	2.2	2.4
As recieved	2.5	3.4
As recieved	3.2	1.6
After the simulated wearing treatment	3.2	2.2
After the simulated wearing treatment	2.6	2.4
After the simulated wearing treatment	3.3	2.7
Mechanical strength and temperature conditioning	3.5	3.3
Mechanical strength and temperature conditioning	3.6	3.2
Mechanical strength and temperature conditioning	3.6	2.6

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	0.4	1.9
As recieved	0.4	1.8
As recieved	0.5	1.8

After temperature conditioning	0.5	1.8
After temperature conditioning	0.4	1.9
After temperature conditioning	0.5	1.8
After the simulated wearing treatment	0.5	1.9
After the simulated wearing treatment	0.5	1.8
After the simulated wearing treatment	0.4	1.9

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	1,6	1,6	1,6	1,6	1,6
As received	1,7	1,6	1,6	1,6	1,6
As received	1,6	1,6	1,6	1,6	1,6
After temperature conditioning	1,7	1,6	1,7	1,6	1,6
After temperature conditioning	1,7	1,6	1,6	1,7	1,6
After temperature conditioning	1,7	1,6	1,6	1,6	1,6
After the simulated wearing treatment	1,7	1,7	1,7	1,6	1,6
After the simulated wearing treatment	1,6	1,6	1,7	1,7	1,7
After the simulated wearing treatment	1,6	1,6	1,6	1,6	1,6

9. DECISION PROPOSAL

Analysis and examinations SO 1553 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 : ERHAN ÜSTÜNEL

SIGN :

DATE : 25.12.2020