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Report No
T1048

12-21

UNIVERSAL SERTİFİKASYON UYGUNLUK DEĞERLENDİRME A.Ş.
Tatlisu Mah. Arif Ay Sk. No:16/3 Umraniye, Istanbul / TURKEY

TEST REPORT

CLIENT and SAMPLE INFORMATION

TEST OWNER	SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.		
ADDRESS	Tatlısu Mah. Akif İnan Sok. No:1, 34774 Ümraniye İSTANBUL TÜRKİYE		
MANUFACTURER	Intelligent Medical Services Producers		
SAMPLE DESCRIPTION	Folding type protective mask		
BRAND NAME / MODEL	IMS FFP2 NR		
SAMPLE RECEIVE DATE	09.12.2021		
STARTING DATE	09.12.2021	FINISH DATE	28.12.2021
REMARKS	-		
NUMBER OF PAGES OF THE REPORT	7		
NUMBER OF SAMPLES	46	SAMPLE IDs	1 – 46
AS RECEIVED SAMPLE NO	26-46		
CONDITIONING SAMPLE NO	Simulated Wearing Treatment		1-2-3-4-5-6-7-8-9 (As Received)
	Temperature Conditioning (T.C.)		10-11-12-13-14-15 (Sample after test of Mechanical Strength)
			16-17-18-19-20-21-22-23-24-25(As Received)
	Mechanical Strength		10-11-12-13-14-15 (As Received)
	Flow Conditioning (Only for particle filtering half masks with valve.)		- (As Received) - (Sample after test of Temperature conditioning)

Universal Certification accredited by TÜRKAK under registration number AB-1693-T for TS EN ISO / IEC 17025:2017 as test laboratory.

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The test and/or measurement results, the uncertainties (if applicable) with confidence probability and test methods are given on the following pages which are part of this report.

Issue Date	Murat Aydemir	Approval
29.12.2021	Responsible of Laboratory	Osman Camcı
		Director

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NOTE 1

The results given in this test report belongs to the samples tested.

NOTE 2

Requirements are taken from the EN 149: 2001 + A1: 2009 standard and the evaluation of results carried out according to these requirements.

NOTE 3

Information about conditioning;

Simulated wearing treatment:

A breathing machine is adjusted to 25 cycles/min and 2,0 l/stroke. The particle filtering half mask is mounted on a Sheffield dummy head. For testing, a saturator was incorporated in the exhalation line between the breathing machine and the dummy head, the saturator being set at a temperature in excess of 37 ºC to allow for the cooling of the air before it reaches the mouth of the dummy head. The air saturated at (37 ±2) ºC at the mouth of the dummy head.

In order to prevent excess water spilling out of the dummy's mouth and contaminating the particle filtering half mask the head inclined so that the water runs away from the mouth and is collected in a trap.

The breathing machine is brought into operation, the saturator switched on and the apparatus allowed to stabilize. The particle filtering half mask under the mounted on the dummy head. During the test time at approximately 20 min intervals the particle filtering half mask completely removed from the dummy head and refitted such that during the test period it is period it is fitted ten times to the dummy head.

Temperature conditioning (T.C.):

Exposed the particle filtering half masks to the following thermal cycle:

a) *For 24 h to dry atmosphere of (70±3) ºC;*
b) *For 24 h to dry atmosphere of (-30±3) ºC;*

And allowed to return room temperature for at least 4 h between exposures and prior to subsequent testing.

The conditioning carried out in a manner which ensured that no thermal shock occurs.

Mechanical strength:

After the masks / strainers are removed from their packaging (if they have seals on them, they are not opened) they are placed in the wide channels on the upper table of the device horizontally and not touching each other.

The device set and operated to operate at 100 revolutions per minute and the conditioning time to be 20 minutes.

As a result of the experiment, it was checked that any deterioration in the masks / strainers or the disassembled parts have not loosened or separated in any way.

Flow conditioning:

A total of 3 valved particle filtering half masks tested, one as received and two temperature conditioned in accordance with temperature.

NOTE 4

Information about evaluation;

Passed	*Results are suitable to requirements.*
Failed	*Results are not suitable to requirements.*
NAs	*Assessment not carried out.*
N/A	*Requirement not applicable.*

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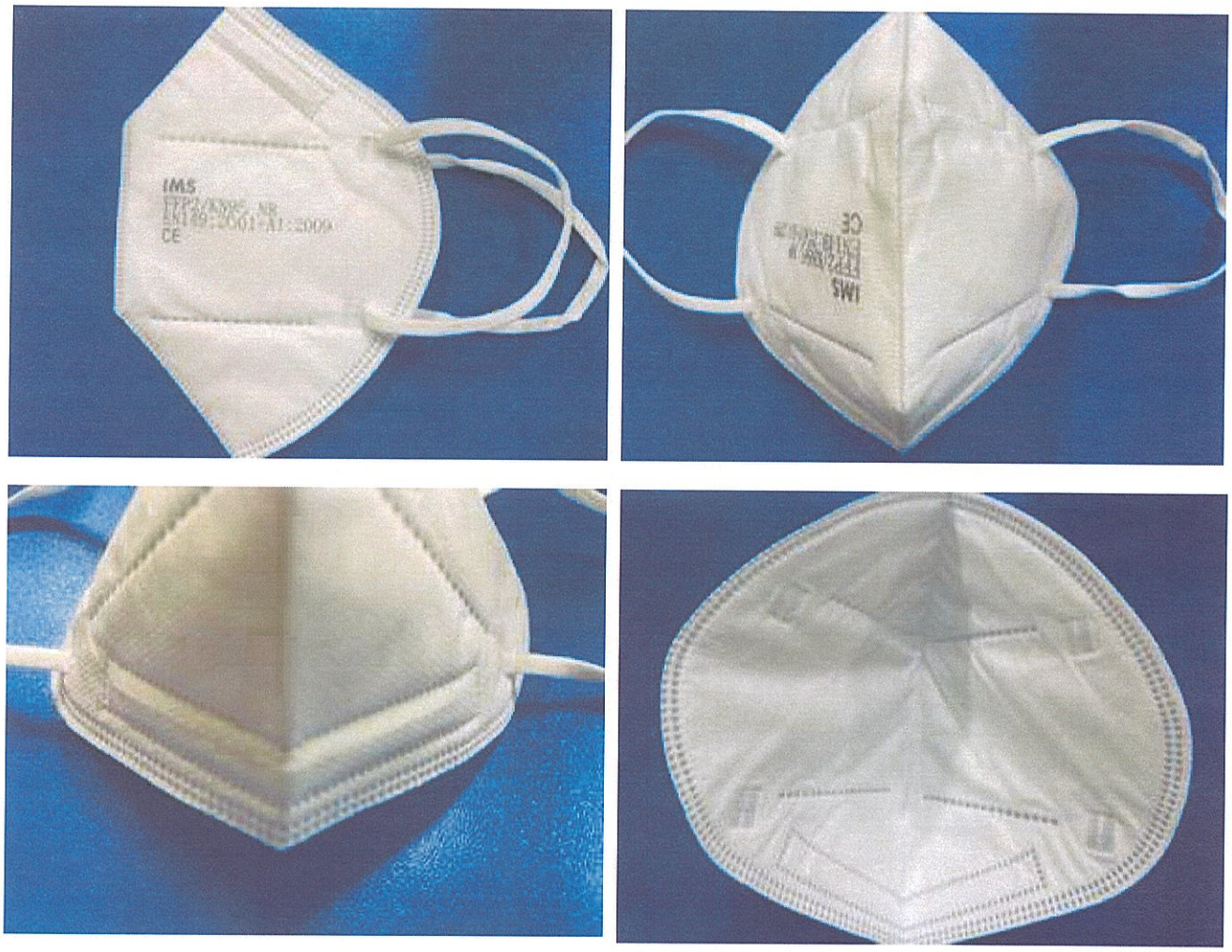
NOTE 5

*In case of conformity assessment, in tests within the scope of TS EN ISO/IEC 17025:2017 accreditation upon customer request; The Simple Acceptance Decision Rule is used. If requested by the customer, the k=2 coverage factor and the measurement uncertainty value at 95% confidence level are specified in the report for the requested tests. Tests marked with * in this report are not included in the scope of accreditation.*

NOTE 6

The experiments were carried out at an ambient temperature of 16-32 degrees.

SAMPLE PHOTOS



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2. TEST RESULTS, REQUIREMENTS and EVALUATION

7.7 PRACTICAL PERFORMANCE

Test Method: EN 149:2001 + A1:2009

The test results obtained are given in the table as follows,

Numbers of samples : 29, 30 (A.R)[1]

ASSESSED ELEMENTS	POSITIVE ASSESSMENT	NEGATIVE ASSESSMENT	RESULTS	REQUIREMENTS	EVALUATION
The face piece fitting	2	0	No imperfections	Filtering half masks should not have imperfections related tc wearer's acceptance.	No evaluation requested.
Head harness comfort	2	0			
Security of fastenings	2	0			
Field of vision					

[1]: *As received*

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7.9.1 TOTAL INWARD LEAKAGE

Test Method: EN 149:2001 + A1:2009

REQUIREMENTS	EVALUATION
The total inward leakage consists of three components: face seal leakage, exhalation valve leakage (if exhalation value fitted) and filter penetration. For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual results shall be not greater than: 25 % for FFP1, 11 % for FFP2, 5 % for FFP3 and in addition at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall not be greater than: 22 % for FFP1, 8 % for FFP2, 2 % for FFP3	No evaluation requested.

The test results obtained are given in the tables as follows,

TEST SUBJECT	NO OF SAMPLE	CONDITION	1. WALK (%)	HEAD SIDE/ SIDE (%)	HEAD UP/DOWN (%)	TALK (%)	2. WALK (%)	AVERAGE (%)
A.K.D	31	A.R.	6,48	7,12	8,04	7,08	8,16	7,37
K.D	32	A.R.	9,31	4,26	5,62	7,16	8,12	6,89
S.G	33	A.R.	7,29	7,54	8,14	8,42	8,19	7,91
Z.Y	34	A.R.	7,46	8,42	7,20	6,63	7,79	7,56
E.C	35	A.R.	3,85	3,78	4,85	5,39	5,03	4,58
M.E	16	T.C.	7,24	10,79	10,72	**13,94**	**13,24**	**11,18**
U.A	17	T.C.	5,43	5,46	4,61	5,35	6,17	5,41
E.D	18	T.C.	2,60	2,14	2,99	2,97	2,98	2,73
A.L	19	T.C.	5,92	7,89	8,53	7,46	6,99	7,35
C.Y	20	T.C.	7,74	6,89	7,20	8,05	6,74	7,32

48 out of the 50 individual exercise results were not greater than 11 %
9 out of the 10 individual wearer arithmetic means were not greater than 8 %

The information in the test subject column is the initial of the candidates who performed the test.

***1.Walk**: walking for 2 min without head movement or talking;*

***Head side/side:** walking turning head from side to side (approximately 15 times), as if inspecting the walls of a tunnel for 2 min;*

***Head up/down:** walking and moving head up and down (approximately 15 times), as if inspecting the ceiling and floor for 2 min;*

***Talk:** walking and reciting the alphabet or an agreed text out loud as if communicating with a colleague for 2 min;*
***2.Walk:** walking for 2 min without head movement or talking*

Test Subject	Face Length (mm)	Face Width (mm)	Face Depth (mm)	Mouth Width (mm)
A.K.D	128	140	136	53
K.D	125	138	140	55
S.G	145	143	140	60
Z.Y	125	135	130	55
E.C	130	140	135	55
M.E	131	135	136	60
U.A	120	140	124	52
E.D	135	130	135	55
A.L	123	145	125	63
C.Y	125	160	145	65

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7.9.2 PENETRATION OF FILTER MATERIAL

Test Method: EN 149:2001 + A1:2009

The test results obtained are given in the tables as follows,

NO. OF SAMPLE	CONDITION	RESULTS Penetration of **Sodium Chloride** in accordance with EN 13274-7:2019 [%] Flow rate 95 l/min	REQUIREMENTS	EVALUATION
36	As received	0,97	FFP1 ≤ 20 % FFP2 ≤ 6 % FFP3 ≤ 1 %	No evaluation requested.
37		1,07		
38		0,80		
1	Simulated wearing treatment	0,87		
2		0,89		
3		0,82		
10	Mechanical strength + Temperature conditioned	3,26		
11		2,74		
12		2,28		

Results for samples 10, 11 and 12 is taken by exposure test. (the mask is loaded 120mg of NaCl)

NO. OF SAMPLE	CONDITION	RESULTS Penetration of **Paraffin Oil** Mist in accordance with EN 13274-7:2019 [%] Flow rate 95 l/min	REQUIREMENTS	EVALUATION
39	As received	0,03	FFP1 ≤ 20 % FFP2 ≤ 6 % FFP3 ≤ 1 %	No evaluation requested.
40		0,22		
41		0,09		
4	Simulated wearing treatment	0,28		
5		0,27		
6		0,14		
13	Mechanical strength + Temperature conditioned	1,01		
14		0,81		
15		0,40		

Results for samples 13,14 and 15 is taken by exposure test. (the mask is loaded 120mg of Paraffin Oil)

7.11 FLAMMABILITY

Test Method: EN 149:2001 + A1:2009

The test results obtained are given in the tables as follows,

NO. OF SAMPLE	CONDITION	VISUAL INSPECTION/ TIME (s)	REQUIREMENTS	EVALUATION
45	As received	0	Filtering half mask shall not burn or not continue to burn for more than 5 s after removal from the flame.	No evaluation requested.
46		0		
21	Temperature conditioned	0		
22		0		

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7.12 CARBON DIOXIDE CONTENT OF THE INHALATION AIR

Test Method: EN 149:2001 + A1:2009

The test results obtained are given in the tabies as follows,

NO. OF SAMPLE	CONDITION	RESULTS CO_2 Content of The Inhalation Air [%] By Volume	RESULTS An Average CO_2 Content of The Inhalation Air [%] By Volume	REQUIREMENTS	EVALUATION
26	As received	0,69	0,71	CO_2 content of the inhalation air shall not exceed an average of 1,0% by volume	No evaluation requested.
27		0,70			
28		0,73			

7.16 BREATHING RESISTANCE

Test Method: EN 149:2001 + A1:2009

The test results obtained are given in the tables as follows,

Inhalation Resistance

NO. OF SAMPLE	CONDITION	FLOW RATE 30 l/min [mbar]	REQUIREMENTS	FLOW RATE 95 l/min [mbar]	REQUIREMENTS	EVALUATION
42	As received	0,40	FFP1 ≤ 0,60	1,77	FFP1 ≤ 2,10	No evaluation requested.
43		0,40		1,80		
44		0,41		1,82		
7	Simulated wearing treatment	0,43		1,77		
8		0,41	FFP2 ≤ 0,70	1,85	FFP2 ≤ 2,40	
9		0,42		1,81		
23	Temperature conditioned	0,40	FFP3 ≤ 1,0	1,80	FFP3 ≤ 3,00	
24		0,41		1,82		
25		0,43		1,82		

Exhalation Resistance

NO. OF SAMPLE	CONDITION	FLOW RATE	Facing directly [mbar]	Facing vertically upwards [mbar]	Facing vertically downwards [mbar]	Lying on the left side [mbar]	Lying on the right side [mbar]	REQUIREMENTS	EVALUATION
42	As received	160 l/min	2,83	2,84	2,82	2,83	2,81	FFP1 ≤ 3,0	No evaluation requested.
43			2,92	2,90	2,88	2,91	2,92		
44			2,94	2,93	2,92	2,95	2,94		
7	Simulated wearing treatment		2,79	2,75	2,77	2,76	2,77		
8			2,81	2,80	2,81	2,80	2,79	FFP2 ≤ 3,0	
9			2,91	2,91	2,90	2,87	2,85		
23	Temperature conditioned		2,90	2,88	2,90	2,85	2,86	FFP3 ≤ 3,0	
24			2,85	2,80	2,82	2,79	2,80		
25			2,83	2,80	2,79	2,80	2,80		

-End of Report-

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