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PERSONAL PROTECTIVE EQUIPMENT EU TYPE-EXAMINATION TEST REPORT

EN 149:2001 + A1:2009
Particle filtering half mask

The examination and testing of Personal Protective Equipment were carried out in accordance with
MSZ EN ISO/IEC 17025:2005 standard
by GÉPTESZT Kft. Notified Body, identified under number 2233 in the EU

Customer:	REX-SAN Medical Device Manufacturer, Distributor and Repairs Kft. Address: 1106 Budapest, Fehér út 10. 22/a, HUNGARY
Model:	REX-SAN RX-01
Classification:	FFP2 NR
Exhalation valve:	NO
Inhalation valve:	NO
Uses:	non reusable (NR)
Project number:	GT396
Test report number:	VD35/396/2109/E/2233
Project worksheet number:	VD-34-2021-396
Date of the test:	2021.08.19-31.
Samples received date:	2021.08.05.
Sample numbers:	396-1 - 396-46
Attachment:	no

Issued: Budapest, 2021.09.16.

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Relevant standards, directives and requirements:

EN 149:2001+A1:2009 Filtering half masks to protect against particles

Description of the sample

The foldable mask is sold in white colour and consists of 5 layers:

1. Outer layer; spun-bonded, non-woven, 50g/m²
2. Filter layer; melt-blown, non-woven, 30g/m²
3. Filter layer; hot air cotton 100% ES, 30g/m²
4. Filter layer; melt-blown, non-woven, 30g/m²
5. Inner layer; spun-bonded, non-woven, 25g/m²

The nose clip is made of Ø0.6mm aluminium dual wire string. The earloop is made of elastane/cotton.



**Short description of EU-type tests:**

Requirement	Test method	Description	Result
7.4	8.2	Packaging	Passed
7.5	8.2	Material	Passed
7.6	8.11	Cleaning and disinfecting	NA
7.7	8.4	Practical performance	Passed
7.8	8.2	Finish of parts	Passed
7.9.1	8.5	Total inward leakage	Passed
7.9.2	8.11	Penetration of filter material: NaCl	Passed
7.9.2	8.11	Penetration of filter material: paraffin oil	Passed
7.10	8.4 and 8.5	Compatibility with skin	Passed
7.11	8.6	Flammability	Passed
7.12	8.7	Carbon dioxide content of the inhalation air	Passed
7.13	8.4 and 8.5	Head harness	Passed
7.14	8.4	Field of vision	Passed
7.15	8.2, 8.3.4, 8.8	Exhalation valve(s)	NA
7.16	8.9	Breathing resistance	Passed
7.17	8.10	Clogging	NA
7.18	8.2	Demountable parts	NA
9	-	Marking	Passed
10	-	Information to be supplied by the manufacturer	Passed

Analysis and details of EU-type test results:**7.4 Packaging**

mask/package	material
1	plastic foil
10	paper box
50	plastic foil

The packaging gives enough protection against mechanical damage or contamination.

PASSED

7.5 Material

- conditioning S.W.: Sample nr: 396-16 to 396-18
None of the particle filtering half masks have suffered mechanical failure of the facepiece or straps.
- conditioning T.C.: Sample nr.: 396-41 to 396-43
Particle filtering half masks did not collapse.

PASSED

7.6 Cleaning and disinfecting (only for reusable masks)

Because the mask is non-reusable, this test was not carried out.

NA

7.7 Practical performance

The particle filtering half masks are tested by practical performance tests under realistic conditions.

1. Walking test for 10 min
2. Work simulation tests:
 - walking on the level with headroom of $(1,3 \pm 0,2)$ m for 5 min;
 - crawling on the level with headroom of $(0,70 \pm 0,05)$ m for 5 min;
 - filling a small basket 20x in 10 min;

Subjects	Samples	Conditioning	Result
MD	396-1	A.R.	PASSED
BI	396-2	A.R.	PASSED

There were not any imperfections related to the wearer's acceptance.

PASSED



7.8 Finish of parts

Parts of the device are likely to come into contact with the wearer have no sharp edges or burrs.

PASSED

7.9.1 Total inward leakage

With sodium chloride aerosol. The masks were in good condition.

Number of subjects were replaced, because of not fitting/facial dimensions:0.....

Subjects facial dimensions				
Subject	Face length, mm	Face width, mm	Face depth, mm	Mouth width, mm
LA	123	140	105	60
MD	117	120	108	60
GL	90	85	80	50
IDZS	118	136	118	45
BP	120	125	116	57
BD	120	130	135	55
RE	115	138	112	48
OJ	130	105	107	54
NT	122	134	142	57
BA	140	155	105	65

Subject	Sample	Cond.	Total inward leakage, %					Mean, %
			Walk	Head left/right	Head up/down	Talk	Walk	
LA	396-3	A.R.	3,17	2,66	2,45	3,03	3,12	2,89
MD	396-4	A.R.	1,69	2,05	2,01	4,07	1,95	2,35
GL	396-5	A.R.	1,72	1,42	1,28	2,41	1,51	1,67
IDZS	396-6	A.R.	2,38	1,42	1,66	2,50	1,88	1,97
BP	396-7	A.R.	1,71	1,72	1,60	2,22	1,67	1,78
BD	396-8	T.C.	2,43	3,10	3,56	5,36	3,25	3,54
RE	396-9	T.C.	1,79	3,67	3,71	3,94	1,46	2,91
OJ	396-10	T.C.	2,49	1,96	1,86	3,93	1,86	2,42
NT	396-11	T.C.	2,76	2,90	3,11	3,98	2,77	3,10
BA	396-12	T.C.	2,89	2,81	2,31	3,05	2,12	2,64

50 out of the 50 individual exercise results for total inward leakage were not greater than 11 % and
10 out of the 10 individual wearer arithmetic means for the total inward leakage were not greater than 8%.

PASSED

7.9.2 Penetration of filter material: NaCl

NaCl aerosol: concentration: 4-12 mg/m³, flow: 95 l/min

Sample	Conditioning	Penetration, %	Exposure, %
396-13	A.R.	0,374	NA
396-14	A.R.	0,24	NA
396-15	A.R.	0,28	NA
396-16	S.W.	2,61	NA
396-17	S.W.	3,09	NA
396-18	S.W.	3,12	NA
396-19	M.S→T.C.	NA	0,31
396-20	M.S→T.C.	NA	0,29
396-21	M.S→T.C.	NA	0,43
Maximum permitted:		6 %	

The penetration of the filter material did not exceed the maximum permitted 6 % in case of any masks.

PASSED

**7.9.2 Penetration of filter material: paraffin oil**Paraffin aerosol: concentration: 15-25 mg/m³, flow: 95 l/min

Sample	Conditioning	Penetration, %	Exposure, %
396-22	A.R.	0,35	NA
396-23	A.R.	0,35	NA
396-24	A.R.	0,43	NA
396-25	S.W.	3,14	NA
396-26	S.W.	3,98	NA
396-27	S.W.	3,83	NA
396-28	M.S→T.C.	NA	1,55
396-29	M.S→T.C.	NA	1,26
396-30	M.S→T.C.	NA	1,83
Maximum permitted:		6 %	

The penetration of the filter material did not exceed the maximum permitted 6 % in case of any masks.

PASSED**7.10 Compatibility with skin**

Materials that may come into contact with the wearer's skin are not known to be likely to cause irritation or any other adverse effect to health.

During the Practical performance test there were no problems.

During the Total inward leakage test there were no problems.

PASSED**7.11 Flammability**

Sample	Conditioning
396-33	T.C.
396-34	T.C.
396-31	A.R.
396-32	A.R.

The materials used do not present a danger for the wearer and are not of highly flammable nature. The samples did not burn.

PASSED**7.12 Carbon dioxide content of the inhalation air**

Air supplied from breathing machine: 25 cycles/min and 2,0 l/stroke, carbon dioxide content of exhaled air 5 V/V%, air flow 0,5 m/s.

Ambient carbon dioxide level: 0,08 % (less than 0,1 %.)

Sample	CO ₂ , V/V%
396-35	0,67
396-36	0,65
396-37	0,68
Average	0,67

The carbon dioxide content of the inhalation air (dead space) did not exceed an average of 1,0 V/V %.

PASSED**7.13 Head harness**

There were no adverse comments regarding security following limited practical performance and total inward leakage testing.

The product satisfied the total inward leakage requirements. See part 7.9.1. for results.

PASSED

**7.14 Field of vision**

Sample
396-1
396-2

During the practical performance test the field of vision was not affected adversely by wearing mask.
PASSED

7.15 Exhalation valve(s)

NA

7.16 Breathing resistance

Sample	Conditioning	Inhalation resistance, mbar		Exhalation resistance, mbar 160 l/min				
		30 l/min	95 l/min	ahead	vert.upwards	vert downwards	left	right
396-38	A.R.	0,18	0,55	0,90	0,91	0,91	0,90	0,89
396-39	A.R.	0,19	0,58	0,96	0,97	0,96	0,95	0,95
396-40	A.R.	0,21	0,62	0,99	1,00	0,99	0,99	0,98
396-41	T.C.	0,16	0,54	0,89	0,91	0,90	0,90	0,89
396-42	T.C.	0,17	0,55	0,88	0,89	0,88	0,87	0,87
396-43	T.C.	0,16	0,53	0,86	0,87	0,86	0,85	0,86
396-44	S.W.	0,17	0,53	0,87	0,88	0,89	0,89	0,87
396-45	S.W.	0,18	0,55	0,91	0,92	0,91	0,90	0,91
396-46	S.W.	0,17	0,54	0,88	0,87	0,87	0,86	0,86
Maximum permitted		0,7	2,4	3,0				

None of the measured values exceeded the maximum values.

PASSED

7.17 Clogging

The optional dolomit clogging test was not required by manufacturer.

NA

7.18 Demountable parts

The device does not contain demountable parts.

NA

9. Marking

The marking information is complete and clearly and durably marked on the packaging.

The marking information is complete and clearly and durably marked on the particle filtering half mask.

PASSED

10. Information to be supplied by the manufacturer

Information to be supplied by the manufacturer accompany every smallest commercial available package and contain all information necessary for trained and qualified persons.

PASSED

Result of EU-type test:

The above described **REX-SAN RX-01 particle filtering half mask** at the time of the test **conformed** to the test requirements of EN 149:2001+A1:2009 class FFP2 NR at the close date of test report.

E N D O F T H E T E S T R E P O R T