

GÉPTESZT Kft.
PPE Approved Test Laboratory

PERSONAL PROTECTIVE EQUIPMENT
EU - TYPE EXAMINATION
TEST REPORT

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.

<u>Test report number:</u>	VD35/145/2009/E/2233	<u>Project number:</u>	GT145
<u>Project worksheet:</u>	VD-34-2020-145	<u>Date of test:</u>	2020.07.28-11.
<u>Customer</u> Printex Medical Klaus Unterseer e. Ko. Address: Annette-Thoma-Weg 6. 83083 Riedering, Germany		<u>Place of test:</u> PPE Testing Laboratory 1032 Budapest, Gyenes St. 12. - Hungary	

Specimen details

Quantity	Received date	Specimen nr.
45	2020.09.04.	145-1 - 145-42

Specimen description and identification:**Model: priuMask particle filtering half mask**

Classification	FFP2
Exhalation valve	-
Inhalation valve	-
Uses	single shift

Relevant standards, directives and requirements: EN 149:2001+A1:2009Short description of EU-type tests:

Requirement	Test method	Description	Passed/Failed/NA
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, 8.9.1,	Exhalation valve(s)	NA
7.16	8.9	Breathing resistance	Passed
7.17	8.10	Clogging	NA
7.18	8.2	Demountable parts	NA

Analysis and details of EU-type test results:

7.4 Packaging

Each mask is packed in a plastic bag, 20 pieces of masks are packed in a cardboard box. It gives enough protection against mechanical damage or contamination.

PASSED

7.5 Material

- conditioning S.W.: Sample nr: 145-25 to 145-27
None of the particle filtering half masks have suffered mechanical failure of the facepiece or straps.
- conditioning T.C.: Sample nr.: 145-8 to 145-10
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
BA	145-1	A.R.	PASSED
RE	145-2	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
NA	130	120	130	50
NT	122	134	142	57
BD	120	130	135	55
DF	108	136	105	55
RE	115	138	112	48
BP	120	125	116	57
LA	123	140	105	60
MD	117	120	108	60
TL	115	130	110	53
BA	140	155	105	65

Subject	Sample	Cond.	Total inward leakage, %					Mean, %
			Walk	Head left/right	Head up/down	Talk	Walk	
NA	145-3	A.R.	1,23	2,45	2,63	4,52	1,53	2,47
NT	145-4	A.R.	2,68	2,97	5,23	4,35	2,08	3,46
BD	145-5	A.R.	3,51	3,89	3,45	4,14	3,11	3,62
DF	145-6	A.R.	4,77	5,30	5,65	6,18	3,79	5,14
RE	145-7	A.R.	1,98	2,11	2,26	2,98	2,43	2,35
BP	145-8	T.C.	3,89	4,26	4,35	4,30	4,08	4,18
LA	145-9	T.C.	4,53	5,16	7,83	5,48	4,87	5,57
MD	145-10	T.C.	5,26	6,63	5,98	8,71	6,01	6,52
TL	145-11	T.C.	2,11	3,63	3,52	3,97	2,05	3,06
BA	145-12	T.C.	6,77	7,50	7,51	7,26	6,29	7,07

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

PASSED

7.9.1 Penetration of filter material: NaCl

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

Sample	Conditioning	Penetration, %	Exposure, %
145-22	A.R.	0,25	NA
145-23	A.R.	0,22	NA
145-24	A.R.	0,28	NA
145-25	S.W.	1,23	NA
145-26	S.W.	1,25	NA
145-27	S.W.	1,21	NA
145-28	M.S→T.C.	NA	0,78
145-29	M.S→T.C.	NA	0,81
145-30	M.S→T.C.	NA	0,73
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/h

Sample	Conditioning	Penetration, %	Exposure, %
145-13	A.R.	0,49	NA
145-14	A.R.	0,51	NA
145-15	A.R.	0,50	NA
145-16	S.W.	1,65	NA
145-17	S.W.	1,01	NA
145-18	S.W.	1,02	NA
145-19	M.S→T.C.	NA	1,45
145-20	M.S→T.C.	NA	1,63
145-21	M.S→T.C.	NA	1,87
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
145-30	T.C.
145-28	T.C.
145-23	A.R.
145-22	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 V/V5 %, 0,5 m/s.

Ambient carbon dioxide level: 09 % (less than 0,1 %.)

Sample	CO ₂ , V/V%
145-31	0,50
145-32	0,64
145-33	0,42

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
145-1
145-2

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		Exhalation resistance 160 l/min				
		30 l/min	95 l/min	ahead	vert. upwards	vert. downwards	left	right
145-34	A.R.	0,42	1,12	1,82	1,90	1,85	1,85	1,83
145-35	A.R.	0,31	1,05	1,53	1,55	1,54	1,55	1,50
145-36	A.R.	0,30	1,07	1,51	1,56	1,53	1,55	1,55
145-37	T.C	0,32	1,03	1,49	1,53	1,52	1,49	1,53
145-38	T.C	0,29	1,0	1,46	1,46	1,41	1,45	1,43
145-39	T.C	0,29	1,03	1,50	1,48	1,49	1,47	1,47
145-40	S.W.	0,33	1,06	1,49	1,53	1,53	1,51	1,54
145-41	S.W.	0,39	1,09	1,66	1,63	1,62	1,67	1,65
145-42	S.W.	0,40	1,08	1,59	1,63	1,63	1,62	1,60
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 has no demountable parts.

NA

Result of EU type test:

The above described **priuMask particle filtering half mask** at the time of the test is **conformed** to the relevant test requirements of EN 149:2001+A1:2009.

Budapest, 2020.09.19.

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