Occupational Safety Research Institute, v.v.i.
Notified Body 1024
Jeruzalémská 1283/9, CZ - 110 00 Praha 1

FINAL REPORT ON CERTIFICATION *
No. 1024/ZZ-023/2020

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I. Source data

Name:	**Respirator BreaSAFE**	
Type:	**ANTI-COVID-19 / FFP2**	
PPE category:	III. according to Regulation (EU) 2016/425 Annex I	
Manufacturer:	PARDAM NANO4FIBERS s.r.o., Žižkova 2759, 413 01 Roudnice nad Labem, Czech Republic	
Application:	S-454/2020	dated: 19. 5. 2020
Contract:	044/2020	dated: 30. 6. 2020
Certified by:	Ing. L. Zavřel	
Date of report issue:	7. 7. 2020	

Výzkumný ústav bezpečnosti práce, v.v.i. Oznámený subjekt 1024 - Notified Body 1024 VÚBP v.v.i. Jeruzalémská 1283/9 Praha 1 Czech Republic

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signature

The product was certified according to Regulation (EU) 2016/425, Module B. The conformity of the product with the essential requirements of this Regulation was carried out in the form of EU type examination.

*This Final report has been issued in Czech and English versions. Both versions have the same validity.

II. Basic information

1. Description of product function and use

The particle filtering half mask **BreaSAFE ANTI-COVID-19 / FFP2 NR** provides the protection of the respiratory system of a user against solid and liquid aerosols in the air in accordance with the information supplied by the manufacturer.

VUBP certificate No. VUBP/024/2020 has already been issued for the respirator. The executor will use the Test report No. 251/2020 together with the results stated therein.

2. Sample withdrawal

Samples of the BreaSAFE FFP2 NR respirator for laboratory tests were supplied by the manufacturer on 16 April 2020 in the number of 8 pieces and on 21 April 2020 in the number of 6 pieces. The samples were registered in the Laboratory Register under numbers 2364 - 2370 and 2611 - 2616.
Additional samples of the respirator for laboratory tests were supplied by the manufacturer on 19 May 2020 in the number of 30 pieces and on 19 June 2020 in the number of 20 pieces. The samples were registered in the Laboratory Register under numbers 4145 - 4174 and 5783 - 5802.

III. List of submitted technical documentation

according to Regulation (EU) 2016/425 Annex III

a)	a complete description of the PPE and of its intended use	+
b)	an assessment of the risks against which the PPE is intended to protect	+
c)	a list of the essential health and safety requirements that are applicable to the PPE	+
d)	design and manufacturing drawings and schemes of the PPE and of its components, sub-assemblies and circuits	+
e)	the descriptions and explanations necessary for the understanding of the drawings and schemes referred to in point (d) and of the operation of the PPE	0
f)	the references of the harmonised standards referred to in Article 14 that have been applied for the design and manufacture of the PPE. In the event of partial application of harmonised standards, the documentation shall specify the parts which have been applied	+
g)	where harmonised standards have not been applied or have been only partially applied, descriptions of the other technical specifications that have been applied in order to satisfy the applicable essential health and safety requirements	0
h)	the results of the design calculations, inspections and examinations carried out to verify the conformity of the PPE with the applicable essential health and safety requirements	0
i)	reports on the tests carried out to verify the conformity of the PPE with the applicable essential health and safety requirements and, where appropriate, to establish the relevant protection class	0
j)	a description of the means used by the manufacturer during the production of the PPE to ensure the conformity of the PPE produced with the design specifications	0
k)	a copy of the manufacturer's instructions and information set out in point 1.4 of Annex II	+

l) for 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	0
m) for PPE produced in series where each item is adapted to fit an individual user, a description of the measures to be taken by the manufacturer during the fitting and production process to ensure that each item of PPE complies with the approved type and with the applicable essential health and safety requirements	0

Evaluation: + available, range is satisfactory; - requirement not fulfilled; 0 not applicable

The submitted technical documentation was found to be complete according to Regulation (EU) 2016/425 ANNEX III and it has been adequate for the assessment of the conformity with the technical requirements mentioned in this Regulation.

IV. Testing

The tests were performed in accordance with:

EN 149:2001+A1:2009 Respiratory protective devices. Filtering half masks to protect against particles. Requirements, testing, marking (idt. ČSN EN 149:2002+A1:2009, ČSN EN 149+A1 OPRAVA 1:2018)

Notice: Report clause numbering is consistent with the above-mentioned standard numbering.

7.3 Visual inspection
Requirement: The visual inspection shall also include the marking and the information supplied by the manufacturer.
Evaluation: Samples have satisfied the requirement

7.4 Packaging
Requirement: Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.
Evaluation: Samples have satisfied the requirement

7.5 Material
Requirement: Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used. After undergoing the simulated wearing treatment none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps. After the temperature conditioning or the simulated wearing treatment the particle filtering half mask shall not collapse. Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.
Evaluation: Samples have satisfied the requirement

7.6 Cleaning and disinfecting
not applicable

7.7 Practical performance
Requirement: The particle filtering half mask shall undergo practical performance tests under realistic conditions.
Discovered: During practical tests no noticeable failures were found.
Evaluation: Samples have satisfied the requirement

7.8 Finish of parts
Requirement: Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.
Evaluation: Samples have satisfied the requirement

7.9 Leakage

7.9.1 Total inward leakage

Requirement: The laboratory tests shall indicate that the particle filtering half mask can be used by the wearer to protect with high probability against the potential hazard to be expected. The total inward leakage consists of three components: face seal leakage, exhalation valve leakage (if exhalation valve fitted) and filter penetration. For particle filtering half masks at least 46 out of the 50 individual exercise results for total inward leakage shall not be greater than 11 % for class FFP2 and, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall not be greater than 8 % for class FFP2.

Discovered:

test subject		sample	condition	exercises					mean
				a)	b)	c)	d)	e)	
1	JH	5787	AR	2,191	1,985	1,636	2,348	3,007	**2,234**
2	JP	5786	AR	0,697	0,861	0,960	1,532	0,733	**0,957**
3	LZ	5785	AR	6,199	6,920	6,769	7,451	6,678	**6,803**
4	RN	5783	AR	10,233	9,913	7,629	15,602	12,946	**11,265**
5	PM	5784	AR	3,418	6,375	4,683	3,151	2,302	**3,986**
6	MDo	5788	TC	13,244	8,918	11,718	10,588	7,578	**10,409**
7	JS	5794	TC	3,643	4,276	2,181	3,003	3,517	**3,324**
8	MBu	5795	TC	3,626	3,382	3,156	3,041	2,696	**3,180**
9	VM	5792	TC	5,122	8,568	5,097	2,772	5,221	**5,356**
10	MN	5793	TC	1,538	1,480	0,812	2,816	0,287	**1,386**
mean				4,991	5,268	4,464	5,230	4,496	**4,890**

Exercises: a) walk only
b) head side to side
c) head up and down
d) reciting an alphabet
e) walk only

AR As received
TC Temperature conditioned

Facial dimensions of test subjects

test subject		face length mm	face width mm	face depth mm	mouth width mm
1	JH	133	165	135	58
2	JP	127	128	138	44
3	LZ	109	132	131	50
4	RN	117	133	134	54
5	PM	113	129	145	55
6	MDo	110	140	104	58
7	JS	118	145	135	59
8	VM	109	126	116	48
9	MBu	113	118	112	51
10	MN	126	133	143	58

Evaluation: Samples have satisfied the requirement

7.9.2 Penetration of filter material

Requirement: The penetration of sodium chloride aerosol shall not exceed for class FFP2 the value of 6 %.

Discovered:

Initial penetration of sodium chloride aerosol

sample	condition	penetration %
2364	AR	5,33
2365	AR	5,16
2366	AR	5,24
4158	MS+TC	3,77
4159	MS+TC	3,63
4160	MS+TC	3,68
4155	SW	5,05
4156	SW	4,35
4157	SW	5,73

Notice: AR - As received
MS - Mechanical strength
TC - Temperature conditioned
SW - Simulated wearing treatment

The highest measured value of penetration of sodium chloride aerosol

sample	condition	penetration %	time of the highest measured value in minutes
4158	MS+TC	3,77	3
4159	MS+TC	3,63	3
4160	MS+TC	3,68	3

Requirement: The penetration of paraffin oil aerosol shall not exceed for class FFP2 the value of 6 %.

Discovered:
Initial penetration of paraffin oil aerosol

sample	condition	penetration %
2367	AR	1,9
2368	AR	2,3
2369	AR	2,1
4145	MS+TC	3,0
4146	MS+TC	2,6
4147	MS+TC	2,7
4157	SW	2,7
4158	SW	4,8
4159	SW	5,4

Penetration of paraffin oil aerosol after exposition of 120 mg oil

sample	condition	penetration %
4145	MS+TC	4,0
4146	MS+TC	3,5
4147	MS+TC	3,6

Evaluation: Samples have satisfied the requirement

7.10 Compatibility with skin
Requirement: Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.
Discovered: The manufacturer submitted the declaration of product effect to health.
Evaluation: Samples have satisfied the requirement

7.11 Flammability

Requirement: The material used shall not present a danger for the wearer and shall not be of highly flammable nature. When tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5 s after removal from the flame.

Discovered: None materials of half mask burn, glow or drip. After passing through the flame, no part of half mask continues to burn, only the surface melts slightly.

Evaluation: Samples have satisfied the requirement

7.12 Carbon dioxide content of the inhalation air

Requirement: The carbon dioxide content of the inhalation air shall not exceed an average of 1 % (by volume).

Discovered:

sample	condition	CO_2 concentration % vol.
2611	AR	0,38
2612	AR	0,44
2613	AR	0,42
mean		0,41

Evaluation: Samples have satisfied the requirement

7.13 Head harness

Requirement: The head harness shall be designed so that the particle filtering half mask can be donned and removed easily. The head harness shall be adjustable or self-adjusting and shall be sufficiently robust to hold the particle filtering half mask firmly in position and be capable of maintaining total inward leakage requirements for the device.

Discovered:

Evaluation: Samples have satisfied the requirement

7.14 Field of vision

Requirement: The field of vision is acceptable if determined so in practical performance tests.

Discovered:

Evaluation: Samples have satisfied the requirement

7.15 Exhalation valve(s)

Not applicable.

7.16 Breathing resistance

Requirement: The inhalation resistance for class FFP2 shall not exceed 70 Pa at flow of 30 l/min and 240 Pa at flow of 95 l/min.

Inhalation resistance

Discovered:

sample	condition	resistance Pa	
		at 30 l/min	at 95 l/min
4154	SW	37	121
4155	SW	37	137
4156	SW	39	115
4151	TC	33	116
4152	TC	33	117
4153	TC	35	131
2364	AR	57	150
2365	AR	65	151
2366	AR	57	155

Requirement: The exhalation resistance for class FFP2 shall not exceed 300 Pa at flow of 160 l/min.

Exhalation resistance

Discovered:

sample	condition	position				
		ahead	down	up	left	right
		Pa	Pa	Pa	Pa	Pa
4154	SW	227	225	227	225	223
4155	SW	267	267	267	265	262
4156	SW	220	220	224	220	220
4151	TC	206	200	205	203	204
4152	TC	208	202	207	205	207
4153	TC	216	209	215	213	214
2364	AR	260	260	262	262	260
2365	AR	256	255	259	250	252
2366	AR	278	276	280	271	272

Evaluation: Samples have satisfied the requirement

7.17 Clogging
Not applicable

7.18 Demountable parts
Not applicable

V. Conformity assessment to the essential requirements

The conformity of the product with all relevant essential health and safety requirements mentioned in Regulation (EU) 2016/425 ANNEX II, has been assessed during EU type examination.

The examination of the manufacturer's technical file, the tests and the evaluations have shown that the submitted model has been designed and manufactured

in accordance with the essential requirements of Regulation (EU) 2016/425, on personal protective equipment,

the following harmonized standards have been used during the assessment: EN 149+A1.

VI. List of documents necessary for The Final report elaboration

1. Regulation (EU) 2016/425 of the European Parliament and of the Council on personal protective equipment and repealing Council Directive 89/686/EEC
2. Application for EU-type examination no. S-454/2020 dated 19. 5. 2020
3. Contract about EU-type examination no. 044/2020 dated 30. 6. 2020
4. Test report no. 251/2020 dated 24. 4. 2020
5. Test report no. 510/2020 dated 22. 6. 2020
6. Test report no. 545/2020 dated 2. 7. 2020
7. Technical documentation, declaration of manufacturer
8. EN 149:2001+A1:2009 Respiratory protective devices. Filtering half masks to protect against particles. Requirements, testing, marking (idt. ČSN EN 149:2002+A1:2009, ČSN EN 149+A1 OPRAVA 1:2018)