

II. Basic information

1. Description of product function and use

Respirator GPP 2 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.

The product meets the class FFP2 requirements.

According to the manufacturer's declaration, the GPP 2 FFP2 NR respirator is identical to the GPP 3 FFP3 NR respirator, for which certificate No. 1024/E-117/2020 (NB 1024) has already been issued. The difference is only in marking. The measurement results are presented in the Final report No. 1024/ZZ-103/2020. The executor will use the Final report No. 1024/ZZ-103/2020 together with the results stated in it

2. Sample withdrawal

see Final report No. 1024/ZZ-103/2020

The samples of respirator GPP 3 FFP3 NR for laboratory tests were supplied by the manufacturer on 17. and 29 September 2020 in the number of 5 and 49 pieces. The samples were registered in the Laboratory Register under numbers 7853 - 7857 and 8135 - 8183.

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	+
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	+

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: see Final report No. 1024/ZZ-103/2020

The respirator has to be fastened with a clip behind the head to achieve the highest possible level of protection. 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: see Final report No. 1024/ZZ-103/2020

All test subjects had respirator connected by a clip behind their head.

test subject	sample	condition	exercises					mean	
			a)	b)	c)	d)	e)		
1	ETi	8156	TC	1,842	5,329	1,995	1,736	3,381	2,857
2	IHe	8157	TC	0,189	0,209	0,267	0,978	0,580	0,445
3	SCh	8158	TC	0,412	0,562	1,133	0,688	1,063	0,772
4	Mdb	8159	TC	0,312	0,676	0,579	1,836	0,948	0,870
5	ZKo	8160	TC	0,336	0,562	0,685	1,937	1,166	0,937
6	FNe	8162	AR	1,207	1,868	2,020	2,102	1,056	1,651
7	LZ	8161	AR	0,495	0,882	0,319	0,181	0,230	0,422
8	MSk	8163	AR	2,425	2,169	2,089	2,787	1,804	2,255
9	JFo	8164	AR	1,931	1,315	1,379	1,309	1,776	1,542
10	JP	8165	AR	1,247	1,616	1,491	2,534	1,408	1,659
mean				1,039	1,519	1,196	1,609	1,341	1,341

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	ETi	118	116	129	54
2	IHe	114	131	126	52
3	SCh	102	111	119	57
4	Mdb	123	117	125	55
5	ZKo	116	129	126	62
6	FNe	123	131	141	48
7	LZ	109	132	131	50
8	MSk	106	126	116	52
9	JFo	114	122	123	56
10	JP	127	128	138	44

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: see Final report No. 1024/ZZ-103/2020

Initial penetration of sodium chloride aerosol

sample	condition	penetration %
8144	MS+TC	0,09
8145	MS+TC	0,05
8146	MS+TC	0,05
8147	AR	0,03
8148	AR	0,02
8149	AR	0,03
8135	SW	0,03
8136	SW	0,03
8137	SW	0,03

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
8144	MS+TC	0,09	3
8145	MS+TC	0,05	3
8146	MS+TC	0,05	3

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

Discovered: see Final report No. 1024/ZZ-103/2020

Initial penetration of paraffin oil aerosol

sample	condition	penetration %
8153	AR	0,049
8154	AR	0,078
8155	AR	0,055
8171	MS+TC	0,094
7854	MS+TC	0,12
7855	MS+TC	0,12
8138	SW	0,051
8139	SW	0,082
8140	SW	0,11

Penetration of paraffin oil aerosol after exposition of 120 mg oil

sample	condition	penetration %
8171	MS+TC	0,18
7854	MS+TC	0,33
7855	MS+TC	0,35

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: see Final report No. 1024/ZZ-103/2020

The manufacturer submits documents in the documentation on the health safety of the materials used.

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: see Final report No. 1024/ZZ-103/2020

None materials of half mask burn, glow or drip. After passing through the flame, no part of half mask continues to burn, only the top layer melts.

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: see Final report No. 1024/ZZ-103/2020

sample	condition	CO ₂ concentration % vol.
7164	AR	0,44
7165	AR	0,41
7166	AR	0,43
mean		0,43

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: see Final report No. 1024/ZZ-103/2020

The respirator has the ear loops, but it is necessary to fasten it with a clip behind the head to achieve the highest possible level of protection

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: see Final report No. 1024/ZZ-103/2020

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: see Final report No. 1024/ZZ-103/2020

sample	condition	resistance Pa	
		at 30 l/min	at 95 l/min
8135	SW	19	98
8136	SW	22	109
8137	SW	22	103
8168	TC	23	88
8169	TC	27	94
8170	TC	26	97
8150	AR	22	96
8151	AR	25	97
8152	AR	25	98

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

Discovered: see Final report No. 1024/ZZ-103/2020

sample	condition	position				
		ahead	down	up	left	right
		Pa	Pa	Pa	Pa	Pa
8135	SW	143	140	142	141	142
8136	SW	152	151	150	150	150
8137	SW	159	160	160	157	158
8168	TC	150	151	150	148	149
8169	TC	149	147	146	149	148
8170	TC	148	148	149	150	150
8150	AR	133	131	132	132	133
8151	AR	137	136	136	135	139
8152	AR	139	139	140	138	139

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 149:2001+A1:2009.



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-824/2020 dated 19. 11. 2020
3. Contract about EU-type examination no. 096/2020 dated 24. 11. 2020
4. Final Report on certification No. 1024/ZZ-103/2020 dated 13. 11. 2020
5. EU type examination certificate No. 1024/E-117/2020 dated 13. 11. 2020
6. Technical documentation, declaration of manufacturer
7. 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)