



Occupational Safety Research Institute, v.v.i.

Notified Body 1024

Jeruzalémská 1283/9, CZ - 110 00 Praha 1

Test Report according to Regulation (EU) 2016/425 *

Report on product check according to Module C2

1024/ZK-018/2020

Pages: 4

Copies: 3

Annexes:

Copy no.: 1

I. Source data

Name: **Filtering half mask to protect against particles RespiPro Carbon**

Type: **4-200-4-4001 FFP2 NR**

PPE category: III. according to Regulation (EU) 2016/425 Annex I

Manufacturer: Respilon Group, s. r. o, Jaselská 14, 602 00 Brno, Czech Republic

Application: S-479/2020 dated: 25. 5. 2020

Contract: 085/2020 dated: 30. 10. 2020

Certificate: 1024/E-013/2019 dated: 30. 4. 2019

Assessed by: Ing. L. Zavřel

signature

Certificate remains valid

About continued
validity of certificate
decided:

Ing. J. Tilhon, Ph.D., LL.M.



signature

Date of report issue: 4. 11. 2020

The product check was performed according to Regulation (EU) 2016/425, Module C2 Conformity to type based on internal production control plus supervised product checks at random intervals

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

II. Basic information

1. Product description

The particle filtering half mask **RespiPro Carbon 4-200-4-4001 FFP2 NR** provides the protection of the respiratory system of a user against solid and liquid aerosols in accordance with the information supplied by the manufacturer.

2. Sample withdrawal

Samples of the half mask RespiPro Carbon 4-200-4-4001 FFP2 NR size L for laboratory tests were taken on 29 September 2020 in the number of 12 pieces. The samples were registered in the Laboratory Register under numbers 8684 - 8695.

III. List of submitted technical documentation

According to the manufacturer's declaration, there has been no change in the product or in the technical documentation.

The complete technical documentation has been already delivered during the product certification in 2019. The documentation is 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. Level determination of protective properties and safety function of the product

On the product has been issued the Certificate no. 1024/E-013/2019 (NB 1024). The measurement results are described in the Final report no. 1024/ZZ-013/2019.

On the basis of the Application no. S-479/2020 and the Contract no. 085/2020 was performed the check of the PPE conformity with the certified type according to EN 149:2001+A1:2009 Respiratory protective devices. Filtering half masks. Requirements, testing, marking (idt. ČSN EN 149:2002+A1:2009, The selected tests on the samples were carried out according to EN 149:2001+A1:2009.

- 8.3.2 temperature conditioning
- 8.3.3 mechanical strength
- 8.9.1 inhalation resistance
- 8.9.2 exhalation resistance
- 8.11 penetration of filter material - paraffin oil

The numbering of articles in the paragraph "Test results" is consistent with the above-mentioned standard numbering.

V. Tests results

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 the temperature conditioning the particle filtering half mask shall not collapse.

Discovered: After test of temperature resistance particle filtering half masks show no visible changes. After the mechanical resistance test, particle filtering half masks show no mechanical flaws.

Evaluation: Samples have satisfied the requirement

7.9.2 Penetration of filter material - paraffin oil

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 %
8684	MS+TC	2,8
8685	MS+TC	2,6
8686	MS+TC	2,7

Notice: MS - Mechanical strength
TC - Temperature conditioned

Penetration of paraffin oil aerosol after exposition of 120 mg oil

sample	condition	penetration %
8684	MS+TC	6,0
8685	MS+TC	5,4
8686	MS+TC	5,2

Evaluation: Samples have satisfied the requirement

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.

Discovered:

sample	condition	breathing resistance Pa	
		flow 30 l/min	flow 95 l/min
8687	TC	47	170
8688	TC	44	169
8689	TC	51	173

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

Discovered:

sample	condition	position				
		ahead	down	up	left	right
		Pa	Pa	Pa	Pa	Pa
8687	TC	200	194	195	194	193
8688	TC	207	205	206	205	206
8689	TC	226	225	225	215	222

Evaluation: Samples have satisfied the requirement

Non-homogeneity checking of production

The non-homogeneity checking of the production was also carried out within the check. The client has chosen the procedure - once per year, take sufficient samples. The non-homogeneity was not found within the check.

VI. Conformity assessment to the essential requirements

The relevant requirements referred to Regulation (EU) 2016/425 ANNEX II, applicable to the final product, were assessed. The harmonized standard EN 149:2001+A1:2009 has been used during the assessment.

The check has confirmed that the tested personal protective equipment

conforms to the type described in the Certificate no. 1024/E-013/2019

and continues to satisfy the relevant essential requirements of Regulation (EU) 2016/425, on personal protective equipment.

VII. List of documents necessary for the 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 check no. S-479/2020 dated 25. 5. 2020
3. Contract about check no. 085/2020 dated 30. 10. 2020
4. Test report no. 710/2020 dated 2. 11. 2020
5. Final report on certification no. 1024/ZZ-013/2019 dated 30. 4. 2019
6. EU type examination certificate no. 1024/E-013/2019 dated 30. 4. 2019
7. Declarations 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)