



**Occupational Safety Research Institute, v.v.i.**

Notified Body 1024

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## FINAL REPORT ON CERTIFICATION \*

### No. 1024/ZZ-036/2022

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Annexes: 0

### I. Source data

Name: **Half mask with filter**

Type: **WF-03 FM P3 NR D**

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

Manufacturer: Wepler Czech s.r.o, Suderova 2013/19a Ostrava - Mariánské hory 70900, Czech Republic

Application: S-084/2022 dated: 10. 3. 2022

Contract: 077/2022 dated: 10. 6. 2022

Certified by:  
Ing. L. Zavřel



signature

Date of report issue: 27. 7. 2022

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.

Distribution list: 1. Manufacturer  
2. NB 1024 archive in electronic form (PDF)

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

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## II. Basic information

### 1. Description of product function and use

**Half mask with filter** against particles **WF-03 FM P3 NR D** provides the respiratory system's protection of a user against solid and liquid aerosols according to the information supplied by the manufacturer.

The product meets the class FM P3 requirements.

Some tests according to the ČSN EN 1827:2000+ A1:2009 standard have already been performed on the WF-03 FM P3 NR D half mask. The executor will use the Test report No. 038/2022 together with the results listed therein.

### 2. Sample withdrawal

Samples of half masks without valves with exchangeable filters were delivered by the manufacturer for laboratory tests on 14 March 2022 in the number of 24 half masks with filters. The samples were registered in the Laboratory register under the numbers 484 – 507. Furthermore, on 27. 04. 2022, new samples with modified seals were delivered by the manufacturer in the number of 6 pcs. The samples were registered in the Laboratory register under numbers 652 – 657.

## 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  | + |
| 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 1827:1999+A1:2009 Respiratory protective devices. Half masks without inhalation valves and with separable filters to protect against gases or gases and particles or particles only. Requirements, testing, marking (idt. ČSN EN 1827:2000+A1:2009)

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

### 7.3 Visual inspection

Requirement: The visual inspection shall include the marking and the information supplied by the manufacturer.

Evaluation: Samples have satisfied the requirement

### 7.4 Materials

Requirement: Materials used shall be suitable to withstand handling and wear over the period for which the half mask is designed to be used. After testing in accordance with test of simulated wearing, inward leakage and practical performance none of the devices shall have suffered mechanical failure of the facepiece body, straps or filter elements.

Discovered: After test of temperature resistance half masks with filters show no visible changes. . After the mechanical resistance test, half masks with filters show no mechanical flaws. After simulated wearing treatment test half masks with filters show no visible changes

Evaluation: Samples have satisfied the requirement

### 7.5 Flammability

Requirement: Parts of a complete device that might be exposed to a flame during use shall not burn or continue to burn for more than 5 s after removal from the flame.

Discovered. Materials of half masks and filters do not burn, glow or drip. After passing through the flame, no part of half mask with filter continues to burn.

Evaluation: Samples have satisfied the requirement

### 7.6 Cleaning and disinfecting

Requirement: Any part of the device designed to be used for more than a single shift (single-use), shall withstand the cleaning and disinfecting agents and procedures recommended by the manufacturer.

Evaluation: Samples have satisfied the requirement

### 7.7 Filter material

Requirement: Any material of the filter media or any gaseous products that may be released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.

Evaluation: Samples have satisfied the requirement

### 7.8 Finish of parts

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

Discovered: Half mask with filter have no sharp parts or burrs.

Evaluation: Samples have satisfied the requirement

### **7.9 Demountable parts**

Requirement: All parts designed to be demountable shall be readily connected and secured, where possible by hand.

Discovered: Filter can be easily replaced.

Evaluation: Samples have satisfied the requirement

### **7.10 Head harness**

**7.10.1** Requirement: The head harness shall be designed so that the device can be donned and removed easily.

**7.10.2** Requirement: The head harness shall be adjustable or self-adjusting and shall be sufficiently robust to hold the device firmly in position and be capable of maintaining inward leakage requirements for the device.

Evaluation: Samples have satisfied the requirement

### **7.11 Connections**

Requirement: The connection between filter(s) and half mask shall be robust and reliable. The connection shall be achieved by use of a special connection. Threads specified in EN 148-1, EN 148-2 or EN 148-3

shall not be used. If a thread connection is used, it shall not be possible to connect this to the threads specified in EN 148-1, EN 148-2 or EN 148-3.

Discovered: The connection between the filter and the facepiece is reliable. The connection of the filter to the half mask is ensured by latches.

Evaluation: Samples have satisfied the requirement

### **7.12 Exhalation valves**

Not applicable.

### **7.13 Packaging**

Requirement: The device and its replaceable parts shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use. Gas and combined filters shall be factory sealed to protect the filter media against environmental influences in such a way, that the breaking of the factory sealing can be identified.

Evaluation: Samples have satisfied the requirement

### **7.14 Mass**

Requirement: The total weight of filter(s) used in devices meeting the requirements of this European Standard shall not exceed 300 g.

Discovered: The mass of one filter is about 64 g.

Evaluation: Samples have satisfied the requirement

### **7.15 Gas filter capacity**

Not applicable.

The half mask with the filter protect only against particles.

### **7.16 Particle filter penetration**

Requirement: The penetration of aerosol of sodium chloride shall not exceed for class FM P3 the value of 0,05 %.

Discovered:

Initial penetration of sodium chloride aerosol

| sample | conditioning | penetration %         |
|--------|--------------|-----------------------|
| 494    | SW           | 0,027                 |
| 495    | SW           | 0,011                 |
| 496    | SW           | less than $1.10^{-2}$ |
| 497    | AR           | 0,019                 |
| 498    | AR           | less than $1.10^{-2}$ |
| 499    | AR           | less than $1.10^{-2}$ |
| 500    | MS+TC        | 0,014                 |
| 501    | MS+TC        | less than $1.10^{-2}$ |
| 502    | MS+TC        | less than $1.10^{-2}$ |

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 | conditioning | penetration %         | time of the highest value measured in minutes |
|--------|--------------|-----------------------|---|
| 500    | MS+TC        | 0,014                 | 3   |
| 501    | MS+TC        | less than $1.10^{-2}$ | 3   |
| 502    | MS+TC        | less than $1.10^{-2}$ | 3   |

Requirement: The penetration of aerosol of paraffin oil shall not exceed for class FM P3 the value of 0,05 %.

Discovered:

Initial penetration of paraffin oil aerosol

| sample | conditioning | penetration %         |
|--------|--------------|-----------------------|
| 484    | AR           | less than $1.10^{-2}$ |
| 485    | AR           | less than $1.10^{-2}$ |
| 486    | AR           | 0,028                 |
| 491    | SW           | less than $1.10^{-2}$ |
| 492    | SW           | less than $1.10^{-2}$ |
| 493    | SW           | less than $1.10^{-2}$ |
| 320    | MS+TC        | less than $1.10^{-2}$ |
| 321    | MS+TC        | less than $1.10^{-2}$ |
| 322    | MS+TC        | less than $1.10^{-2}$ |

Penetration of paraffin oil aerosol after exposition 120 mg oil

| sample | conditioning | penetration %         |
|--------|--------------|-----------------------|
| 320    | MS+TC        | less than $1.10^{-2}$ |
| 321    | MS+TC        | less than $1.10^{-2}$ |
| 322    | MS+TC        | less than $1.10^{-2}$ |

Evaluation: Samples have satisfied the requirement

## 7.17 Clogging

### 7.17.2 Filter penetration

Requirement: The penetration after glogging shall not exceed for class FM P3 the value of 0,05 %.

Discovered:

| sample | conditioning | NaCl penetration %          | paraffin oil penetration %  |
|--------|--------------|-----------------------------|-----------------------------|
| 503    | AR           | 0,010                       | less than $1 \cdot 10^{-2}$ |
| 504    | TC           | 0,014                       | less than $1 \cdot 10^{-2}$ |
| 505    | TC           | less than $1 \cdot 10^{-2}$ | less than $1 \cdot 10^{-2}$ |

Evaluation: Samples have satisfied the requirement

### 7.17.3 Breathing resistance

#### 7.17.3.2 Devices without exhalation valves

Requirement: The inhalation resistance and the exhalation resistance for class FM P3 shall not exceed 500 Pa at flow 95 l/min.

Discovered:

| sample | conditioning | inhalation resistance Pa | exhalation resistance Pa |
|--------|--------------|--------------------------|--------------------------|
| 503    | AR           | 197                      | 194                      |
| 504    | TC           | 185                      | 179                      |
| 505    | TC           | 180                      | 166                      |

Evaluation: Samples have satisfied the requirement

### 7.18 Compatibility with skin

Requirement: Materials that can 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: Based on the submitted documentation the material is not known to could cause any adverse effect to health.

Evaluation: Samples have satisfied the requirement

### 7.19 Carbon dioxide content of inhalation air

Requirement: The carbon dioxide content of the inhalation air shall not exceed an average of 1,0 % by volume.

Discovered:

| sample      | conditioning | CO <sub>2</sub> concentration % vol. |
|-------------|--------------|--------------------------------------|
| 323         | AR           | 0,80                                 |
| 324         | AR           | 0,88                                 |
| 325         | AR           | 0,85                                 |
| <b>mean</b> |              | <b>0,84</b>                          |

Evaluation: Samples have satisfied the requirement

### 7.20 Breathing resistance without clogging

#### 7.20.2 Inhalation resistance

##### 7.20.2.3 Half masks with particle filters

Requirement: The inhalation resistance for class FM P3 shall not exceed 120 Pa at flow 30 l/min and 420 Pa at flow 95 l/min.

Discovered:

| sample | conditioning | breathing resistance Pa |          |
|--------|--------------|-------------------------|----------|
|        |              | 30 l/min                | 95 l/min |
| 491    | SW           | 51                      | 170      |
| 492    | SW           | 53                      | 177      |
| 493    | SW           | 51                      | 164      |
| 652    | TC           | 50                      | 163      |
| 653    | TC           | 51                      | 168      |
| 654    | TC           | 60                      | 186      |
| 323    | AR           | 55                      | 165      |
| 324    | AR           | 50                      | 163      |
| 325    | AR           | 49                      | 153      |

Evaluation: Samples have satisfied the requirement

### 7.20.3 Exhalation resistance

Requirement: The exhalation resistance of the complete device at flow 160 l/min shall not exceed 300 Pa.

Discovered:

| sample | conditioning | breathing resistance Pa |
|--------|--------------|-------------------------|
|        |              | při 160 l/min           |
| 491    | SW           | 284                     |
| 492    | SW           | 290                     |
| 493    | SW           | 270                     |
| 652    | TC           | 264                     |
| 653    | TC           | 273                     |
| 654    | TC           | 260                     |
| 323    | AR           | 258                     |
| 324    | AR           | 250                     |
| 325    | AR           | 250                     |

Evaluation: Samples have satisfied the requirement

### 7.21 Inward leakage

Requirement: For half masks fitted in accordance with the information supplied by the manufacturer, at least 46 out of the 50 individual results for the inward leakage over each of the exercise periods as defined in 8.12.7 (i.e. 10 subjects x 5 exercise periods) shall be not greater than 5 % and, in addition, at least 8 out of the 10 individual wearer arithmetic means (10 subjects) for the inward leakage, averaged over all exercise periods shall be not greater than 2 %.

Discovered:

| test subject  | sample | con-<br>dition | exercises |              |              |              |              | mean         |              |
|---------------|--------|----------------|-----------|--------------|--------------|--------------|--------------|--------------|--------------|
|               |        |                | a)        | b)           | c)           | d)           | e)           |              |              |
| 1             | JFo    | 652            | TC        | 0,625        | 1,056        | 1,148        | 0,986        | 0,543        | <b>0,872</b> |
| 2             | LZ     | 655            | TC        | 0,204        | 0,866        | 0,689        | 0,207        | 0,152        | <b>0,424</b> |
| 3             | JBo    | 655            | TC        | 0,291        | 0,143        | 0,529        | 0,419        | 0,348        | <b>0,346</b> |
| 4             | JT     | 652            | TC        | 0,209        | 0,197        | 0,272        | 0,342        | 0,275        | <b>0,259</b> |
| 5             | JS     | 655            | TC        | 0,874        | 0,910        | 0,886        | 0,820        | 0,821        | <b>0,862</b> |
| 6             | PM     | 656            | AR        | 0,796        | 1,120        | 0,971        | 0,563        | 0,913        | <b>0,873</b> |
| 7             | MDr    | 656            | AR        | 0,102        | 1,120        | 0,816        | 0,325        | 0,385        | <b>0,550</b> |
| 8             | JH     | 657            | AR        | 0,467        | 0,449        | 0,461        | 0,385        | 0,452        | <b>0,443</b> |
| 9             | JU     | 657            | AR        | 0,166        | 0,326        | 0,355        | 0,338        | 0,271        | <b>0,291</b> |
| 10            | MZ     | 657            | AR        | 2,607        | 2,415        | 1,291        | 0,064        | 0,403        | <b>1,356</b> |
| <b>průměr</b> |        |                |           | <b>0,634</b> | <b>0,860</b> | <b>0,742</b> | <b>0,445</b> | <b>0,456</b> | <b>0,627</b> |

Exercises: a) walk only

b) head side to side

AR As received

- c) head up and down
- d) reciting an alphabet
- e) walk only

TC Temperature conditioned

#### Facial dimensions of test subjects

| test subject |     | face length<br>mm | face width<br>mm | face depth<br>mm | mouth width<br>mm |
|--------------|-----|-------------------|------------------|------------------|-------------------|
| 1            | JFo | 114               | 122              | 123              | 56                |
| 2            | LZ  | 109               | 132              | 131              | 50                |
| 3            | JBo | 104               | 145              | 104              | 60                |
| 4            | JT  | 121               | 126              | 138              | 54                |
| 5            | JS  | 118               | 145              | 135              | 59                |
| 6            | PM  | 113               | 129              | 145              | 55                |
| 7            | MDr | 128               | 132              | 133              | 56                |
| 8            | JH  | 133               | 165              | 135              | 58                |
| 9            | JU  | 114               | 117              | 129              | 54                |
| 10           | MZ  | 111               | 129              | 135              | 59                |
| 1            | JFo | 114               | 122              | 123              | 56                |

Evaluation: Samples have satisfied the requirement

#### 7.22 Field of vision

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

Evaluation: Samples have satisfied the requirement

#### 7.23 Practical performance

Requirement: The device shall undergo practical performance tests under realistic conditions. Where practical performance tests show the apparatus has imperfections related to wearer's acceptance, the test house shall provide full details of those parts of the practical performance tests which revealed these imperfections.

Discovered: Both test subjects complained, that the half-mask pressed uncomfortably on the face when tightened more, primarily in the nose area. No other negative comments from testers.

Evaluation: Samples have satisfied the requirement

## 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 1827:1999+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-084/2022 dated 10. 3. 2022
3. Contract about EU-type examination no. 077/2022 dated 10. 6. 2022
4. Test report no. 038/2022 dated 10. 2. 2022
5. Test report no. 090/2022 dated 22. 4. 2022
6. Test report no. 118/2022 dated 3. 6. 2022
7. Technical documentation, declaration of manufacturer
8. EN 1827:1999+A1:2009 Respiratory protective devices. Half masks without inhalation valves and with separable filters to protect against gases or vapours and particles or particles only. Requirements, testing, marking (idt. ČSN EN 1827:2000+A1:2009)