# EVALUATION OF THE CONFORMITY

**2021EC0051UE**

**APPLICATION DATE**
14/01/2021

**APPLICANT**

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Att.

**IDENTIFICATION AND DESCRIPTION OF SAMPLES**

| REFERENCES |
|---|
| DM-002 |
| **Description**<br><br>Filtering half mask covering mouth, nose and chin, white colour |

**TESTS CARRIED OUT**

- OBSERVATIONS
- DESCRIPTION OF SAMPLE
- ESSENTIAL REQUIREMENTS
- EVALUATION FOR EU TYPE CERTIFICATION





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# OBSERVATIONS

The PPE type filtering half mask to protect against covid-19 only referenced as DM-002, has been presented for the “EU” Type certification with compliance with Regulation (EU) 2016/425 and the technical specifications applicable to it, according to the Recommendation for Use RfU PPE-R/02.075 version 2 according to Commission Recommendation (EU) 2020/403 of 13 March 2020 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat.

The manufacturer has presented the applicable Technical Documentation according to Annex II of the Regulation (EU) 2016/425.

For the certification, the manufacturer presents following samples:

- Thirty (30) PPE TYPE filtering half mask with valve to protect against COVID-19 Ref. DM-002.

The CAT. III PPE shall only be used in conjunction with one of the conformity assessment procedures according to Module C2 or Module D described in Article 19 letter c) of the Regulation (EU) 2016/425.

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# SAMPLE DESCRIPTION

FILTERING HALF MASK referenced as DM-002

Particle filtering half mask without exhalation valve covering nose, mouth and chin, white colour.

The particle filtering half mask has ear bands and nose clip.

In this particle filtering half mask, air enters the mask through the body and goes directly to the inner area of the main body of the particle filtering half mask. The exhaled air returns to the atmosphere through the main body and valve of the particle filtering half mask.

The PPE is manufactured according to documentation presented by the customer:

Protective respirator DM-002 is made 4 layers of:

- 50 gsm Spundond Nonwoven Fabric;
- 40 gsm Meltblown Nonwoven Fabric;
- 40-50 gsm Hot air Nonwoven Fabric;
- 25 gsm Spunbond Nonwoven Fabric;
- Earbands;
- Adjustable sealed Nose Clip;
- Half-fold shell and cup design;
- Marking.

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# ESSENTIAL HEALTH AND SAFETY REQUIREMENTS

The following table shows the correlation between the essential health and safety requirements of Regulation 2016/425 of 9th march 2016 "Personal Protective Equipment" and the articles of the Recommendation for Use RfU PPE-R/02.075 version 2 according to Commission Recommendation (EU) 2020/403 of 13 March 2020 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat.

| Annex II Regulation 2016/425 | Clauses of Standard PPE-R/02.075 version 2 |
|---|---|
| 1.1.1 Ergonomics | 3.7; 3.9 |
| 1.1.2.1. Optimum level of protection | 3.7; 3.9; 3.11 |
| 1.1.2.2. Classes of protection appropriate to different levels of risk | 3.9 |
| 1.2.1. Absence of inherent risks and other nuisance factors. | 3.6; 3.11; 3.13; 3.15 |
| 1.2.1.1. Suitable constituent materials | 3.5; 3.6; 3.7; 3.10 |
| 1.2.1.2. Satisfactory Surface condition of all PPE in contact with the user | 3.7; 3.8 |
| 1.2.1.3. Maximum permissible user impediment. | 3.7;3.13 |
| 1.3.1 Adaptation of PPE to user morphology | 3.7 |
| 1.3.2. Lightness and strength | 3.4; 3.5; 3.7 |
| 1.4. Manufacturer's instructions and information | 5 |
| 2.1. PPE incorporating adjustment systems. | 3.12 |
| 2.3. PPE for the face, eyes and respiratory system. | 3.13 |
| 2.4. PPE subject to ageing | 3.6; 4; 5 |
| 2.6. PPE for use in potentially explosive atmospheres. | 5 |
| 2.8. PPE for intervention in very dangerous situations. | 5 |
| 2.9. PPE incorporating components which can be adjusted or removed by the user | 3.12; 3.16 |
| 2.12. PPE bearing one or more identification markings or indicators directly or indirectly relating to health and safety. | 4 |
| 3.10.1. Respiratory protection. | 3.6; 3.7; 3.8; 3.9; 3.11; 3.15; 4; 5 |

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# EVALUATION

The PPE type filtering half mask to protect against only covid-19 referenced as DM-002, has been evaluated, according to Regulation (EU) 2016/425 and the technical specifications applicable to it, according to the Recommendation for Use RfU PPE-R/02.075 version 2 according to Commission Recommendation (EU) 2020/403 of 13th of March 2020 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat.

## 1.- TECHNICAL DOCUMENTATION AND MARKING

| | RELATED DOCUMENT | ANNEX / CLAUSE | RESULTS |
|---|---|---|---|
| Technical documentation. | Regulation (UE) 2016/425 | Annex III | Achieved |
| Marking | Regulation (UE) 2016/425 | Article 17 | Achieved |
| | PPE-R/02.075 | 4 | |
| Manufacturer information * | Regulation (UE) 2016/425 | Annex II point 1.4 | Achieved |
| | PPE-R/02.075 | 5 | Achieved |

* It has been verified about the version in English presented by the client.

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# EVALUATION

## 2.- REQUIREMENTS

### 2.1.- VISUAL INSPECTION

#### 2.1.1- ACCORDING TO THE STANDARD PPE-R/02.075 version 2

| TEST | CLAUSE | REQUIREMENT | RESULT | REPORT No. |
|---|---|---|---|---|
| Packaging | 3.4 | Filtering half mask shall be packaged to protect them from mechanical damage, thermal and contaminant conditions during storage. | Achieved | 2021EC0051UE |
| Materials | 3.5 | 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.<br>Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer. | Achieved | 2020EC4785 |
| Cleaning and desinfection | 3.6 | If the particle filtering half mask is designed to be cleaned and disinfected, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer.<br>Cleaning and disinfection method can be accepted only if they are scientifically proved in peer reviewed scientific publications effective against the SARS-CoV-2, or have been recommended by European Centre for Disease Prevention and Control, ECDC<br>After cleaning and disinfecting the particle filtering half mask shall satisfy the penetration requirement. | N.A | --- |
| Finished of parts | 3.8 | Parts of the equipment that can be contact with the user shall not have sharp edges or burrs. | Achieved | 2020EC4785 |
| Exhalation valve | 3.14 | If an exhalation valve is available, it should be protected against, or resistant to, dirt and mechanical damage and can be covered or include any other necessary devices. | N.A | --- |

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# EVALUATION

### 2.2.- TESTS

#### 2.2.1- ACCORDING TO THE STANDARD PPE-R/02.075 version 2

| TEST | CLAUSE | REQUIREMENT | RESULT | REPORT No. |
|---|---|---|---|---|
| Filter penetration | 3.9 | The penetration of the filter of the filtering half mask shall be 6% as maximum for NaCl aerosol. | Achieved | 2020EC4785 |
| Content CO2 of inhaled air. | 3.11 | The carbon dioxide content of the inhaled air should not exceed on average 1% (by volume). | Achieved | 2020EC4785 |
| Breathing resistance | 3.15 | Max. Resistance Inhalation at 30L / min 2,4 mbar<br>Resistencia máx. exhalación a 160L/min: 3 mbar /<br>Max. Resistance exhalation at 160L / min 3 mbar | Achieved | 2020EC4785 |
| Practical behavior | 3.7 | The filtering half mask should maintain a good face seal with the user. | Achieved | 2020EC4785 |
| | 3.10 | Compatibility with skin<br>Materials that may be in contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health. | Achieved | 2020EC4785 |
| | 3.12 | The head harness shall be designed so that the filtering half mask can be donned and removed easily.<br>The head harness shall be adjustable or self-adjusting and shall be sufficiently robust to hold the filtering half mask firmly in position. | Achieved | 2020EC4785 |
| | 3.13 | A field of vision should be considered as acceptable, if so determined in the practical behavior test. | Achieved | 2020EC4785 |

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***Head of Advance Personal Protective Equipment Lab.***

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