CONFORMITY ASSESSMENT

2020EC4257UE

DATE OF RECEPTION
05/10/2020

APPLICANT

GOOD MASK s.r.o.
Balbinova 529/1, 120 00 Prague 2
CZ-12000 PRAHA

Att. Martin Ladyr

IDENTIFICATION AND DESCRIPTION OF SAMPLES

REFERENCES
GOOD MASK GM2 respirator
Description: Particle filtering half mask without exhalation valve covering nose, mouth and chin, white colour

TESTS CARRIED OUT

- OBSERVATIONS
- DESCRIPTION OF SAMPLE
- ESSENTIAL REQUIREMENTS
- EVALUATION
- CONCLUSION OF THE CONFORMITY EVALUATION

ENAC is a signatory to the Multilateral Agreement (MLA), (MRA Mutual Recognition Agreement) of the European Cooperation for Accreditation (EA) and the International Laboratory Accreditation Cooperation (ILAC), in tesing.

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OBSERVATIONS

The PPE type filtering half mask to protect against only covid-19 referenced as GOOD MASK GM2 respirator, 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 the following samples:

- Thirty (30) PPE TYPE valveless filtering half mask to protect against COVID-19 Ref. GOOD MASK GM2 respirator.

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 GOOD MASK GM2 respirator

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

The particle filtering half mask has ear bands joined by a piece made with white plastic 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.

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

- Outer fabric: non-woven fabric.
- Second and third layer: meltblown.
- Inner fabric: non-woven hypoallergenic fabric.
- Ear band: elastic.
- Nose clip with metal and sponge.

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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 GOOD MASK GM2 respirator, 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 Spanish 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	2020EC4257UE
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. 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	2020EC4256
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. 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 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	2020EC4256
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	---
Demountable parts	3.16	All removable parts (if any) shall be connected and secured easily and, whenever possible, manually.	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	2020EC4256
Content CO2 of inhaled air.	3.11	The carbon dioxide content of the inhaled air should not exceed on average 1% (by volume).	Achieved	2020EC4256
Breathing resistance	3.15	Max. Resistance Inhalation at 30L / min 2,4 mbar Resistencia máx. exhalación a 160L/min: 3 mbar / Max. Resistance exhalation at 160L / min 3 mbar	Achieved	2020EC4256
Practical behavior	3.7	The filtering half mask should maintain a good face seal with the user.	Achieved	2020EC4256
	3.10	Compatibility with skin 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	2020EC4256
	3.12	The head harness shall be designed so that the 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 filtering half mask firmly in position.	Achieved	2020EC4256
	3.13	A field of vision should be considered as acceptable, if so determined in the practical behavior test.	Achieved	2020EC4256

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CONCLUSION OF THE CONFORMITY EVALUATION

AITEX, as Notified Body No. 0161, concludes that:

The PPE TYPE filtering half mask to protect against only covid-19 referenced as GOOD MASK GM2 respirator, complies with the essential health and safety requirements in accordance with the provisions of 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 results of the tests carried out, as well as the evaluations, are valid only for the tested PPE.

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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Israel Soriano

Head of Advance Personal Protective Equipment Lab.

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LIABILITY CLAUSES

1.- AITEX is liable only for the results of the methods of analysis used, as expressed in the report and referring exclusively to the materials or samples indicated in the same which are in its possession, the professional and legal liability of the Centre being limited to these. Unless otherwise stated, the samples were freely chosen and sent by the applicant.
2.- AITEX shall not be liable in any case of misuse of the test materials nor for undue interpretation or use of this document
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4.- In the eventuality of discrepancies between reports, a check to settle the same will be carried out in the head offices of AITEX. Also, the applicants undertake to notify AITEX of any complaint received by them as a result of the report, exempting this Centre from all liability if such is not done, the periods of conservation of the samples being taken into account.
5.- AITEX is not responsible for the information provided by customers, which is reflected in the Report, and may affect the validity of the results.
6.- AITEX will provide at the request of the person concerned, the treatment of complaints procedure.
7.- AITEX is not responsible for an inadequate state of the sample received that could compromise the validity of the results, expressing such circumstance, in the test reports.
8.- AITEX may include in its reports, analyses, results, etc., any other evaluation which it considers necessary, even when it has not been specifically requested.
9.- When a Declaration of Conformity is requested, if not indicated otherwise, the decision rule will be applied according to ILAC-G8 & ISO 10576-1, in case of ambiguity, or indeterminacy
10.- The uncertainties of tests, which are made explicit in the Results Report, have been estimated for a k = 2 (95% probability of coverage). If not informed, they are available to the client in AITEX.
11. - The original materials and rests of samples, not subject to test, will be retained in AITEX during the twelve months following the issuance of the report, so that any check or claim which, in his case, wanted to make the applicant, should be exercised within the period indicated.
12.- This report may only be sent or delivered by hand to the applicant or to a person duly authorised by the same.
13.- The results of the tests and the statement of compliance with the specification in this report refer only to the test sample as it has been analyzed / tested and not the sample / item which has taken the test sample.
14.- The client must attend at all times, to the dates of the realization of the tests.
15.- According to Resolution EA (33) 31, the test reports must include the unique identification of the sample, and any brand or label of the manufacturer may be added. It is not allowed to re-issue test reports of untested sample names (references), they can only be re-issued for error correction or inclusion of omitted data that were already available at the time of the test. The laboratory can not assume responsibility for declaring that the product with the new trade name / trademark is strictly identical to the one originally tested; This responsibility belongs to the client.
16.- This report may not be partially reproduced without the written approval of the issuing laboratory.