

EU Type-Examination Certificate

Regulation on Personal Protective Equipment (Module B) Temporary approval of filtering half mask to protect against COVID-19 Certificate No.: 0200-PPE-09328 version 1

FORCE Certification A/S (EU-notified body number 0200) has in accordance with the provisions of Recommendation for use No. PPE-R/02.075 and the basic principles of Regulation (EU) 2016/425 of The European Parliament and of The Council of 9 March 2016, issued a temporary EU type-examination certificate to:

Manufacturer:

Alialux SRL
Italy

For manufacturing the following personal protective equipment:

Type/Description:

Filtering half mask to protect against COVID-19

Model/Designation:

AXMASH-GEN

Test scheme:

Recommendation for use PPE-R/02.075 version 2

Category:

III

Restrictions for use:

Temporary and limited approval of filtering half mask to protect against COVID-19. This filtering half mask is not a filtering half mask for general use and shall not be used for purposes other than protection against COVID-19.

The examined sample of personal protective equipment is found to fulfill the relevant requirements of the applied test scheme(s) and to be in compliance with the applicable essential health and safety requirements of Regulation (EU) 2016/425. Documentation for observance of relevant requirements and the basis for the type examination are described in the appendix to this certificate. The manufacturer shall inform FORCE Certification A/S of any contemplated changes.

The validity of this conformity assessment certificate is less than one year. Annual production control according to Regulation (EU) 2016/425 module C2 or D have not been assessed. The certificate may be prolonged following a re-examination of the product(s).

Date of issue: **2020-11-18**

Date of expiry: **2021-05-18**



Kasper Munk Eliasen
Certification Manager



Erik Bjarnov
Examiner

FORCE Certification A/S task No.: **120-30960**/ Certificate ID: **09328**

This certificate will remain valid unless cancelled, revoked or expired, provided the conditions in the attached appendix are complied with, and that the equipment remains state of the art within its applicable field of service. Status of this certificate can be verified on www.forcecertification.com. This EU Type-Examination Certificate is the property of FORCE Certification A/S. Extracts of this certificate may only be reproduced with a written permission from FORCE Certification A/S.

Appendix to EU type-examination certificate

Temporary and limited approval of
filtering half mask to protect against COVID-19

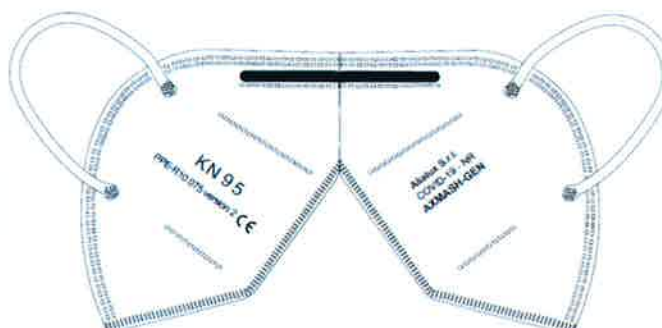
Certificate No.: 0200-PPE-09328 version 1
Issued by FORCE Certification A/S - EU-notified body number 0200

Manufacturer: Alialux SRL
Via Napoli 42
21021 Angera (VA)
Italy

Identification of personal protective equipment:

Type/Description: Filtering half mask to protect against COVID-19
Model/Designation: AXMASG-GEN
Test scheme: Recommendation for use PPE-R/02.075 version 2
Restrictions for use: Temporary and limited approval of filtering half mask to protect against COVID-19. This filtering half mask is not a filtering half mask for general use and shall not be used for purposes other than protection against COVID-19.
Category: III

Design:



AXMASG-GEN

History:

| Issue/change: | Certificate No.: | Certificate ID: | Issue date: |
|------------------------|--------------------------|-----------------|-------------|
| - Original certificate | 0200-PPE-09328 version 1 | 09328 | 2020-11-18 |

Place(s) of Production:

| Final assembly | Address |
|---|--|
| - Fangrui (Jiashan) Labor Protection Products Co., Ltd. | Building 4, No.79 Zhijang Road, Huimin Sreet, Jiashan County, Jiaxing City, Zhejiang Province. China |

Appendix to EU type-examination certificate

Temporary and limited approval of
filtering half mask to protect against COVID-19

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Documentation for observance of relevant technical requirements stated in the applied test scheme:

| Test house | Report No.: | Testing/Inspection of: |
|--------------------|-------------|---|
| - FORCE Technology | 120-30960 | Type-testing of filtering half mask according to PPE-R/02.075 version 2 |

Partial conclusion: The requirements stated in the applied test scheme are fulfilled for the relevant test clauses and nominal protection factor.

Further documentation for observance of relevant/limited requirements stated in Annex III of Regulation (EU) 2016/425:

- Risk assessment: OK, integrated part of application
- List of applicable EHSR OK, integrated part of application and in tech file
- List of materials and sub-suppliers OK, drawings and bill of materials
- Agreements between Alialux and Fangrui Affidavits for transfer of qualification for OBL and for Original manufacturer Both Dated 13/10-2020
Fascicolo Tecnico semimaschera filtrante OBL Alialux DRAFT C EN.pdf
Fascicolo Tecnico semimaschera filtrante OEM Fangrui rev. 01 ERRATA CORRIGE EN.pdf
- Description of quality system OK, description of QS System received
- User information and marking OK, markings on mask, received 2020-11-17
OK, markings on packaging, received 2020-11-17
OK, user manual, received 2020-11-17
- Declaration of innocuousness OK, integrated part of application

The user information and marking was assessed in English.

Conclusion

Based on the above-mentioned attestation it can be concluded that the filtering half mask to protect against COVID-19, designated AXMASH-GEN, meets the conditions of a temporary and limited approval according to Regulation (EU) 2016/425.

FORCE Certification A/S task No.: 120-30960
Date: 2020-11-18


Erik Bjarnov
Examiner