

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-08909 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:

MaskMakers Sweden AB

For manufacturing the following personal protective equipment:

Type/Description:

Filtering half mask to protect against COVID-19

Model/Designation:

MM-HM-201

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 [yyyy-mm-dd]: **2020-09-09**

Date of expiry [yyyy-mm-dd]: **2021-03-09**



Philippa W. Osted
Certification Manager



Kasper Munk Eliassen
Examiner

FORCE Certification A/S task No.: **120-30082** / Certificate ID: **08909**

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-08909 version 1
Issued by FORCE Certification A/S - EU-notified body number 0200

Manufacturer: MaskMakers Sweden AB
Förrådsvägen 23
SE-741-30 Knivsta
Sweden

Identification of personal protective equipment:

Type/Description: Filtering half mask to protect against COVID-19
Model/Designation: MM-HM-201
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:



MM-HM-201

Appendix to EU type-examination certificate
Temporary and limited approval of
filtering half mask to protect against COVID-19

Certificate No.: 0200-PPE-08909 version 1
Issued by FORCE Certification A/S - EU-notified body number 0200

History:

Issue/change:	Certificate No.:	Certificate ID:	Issue date:
- Original certificate	0200-PPE-08909 version 1	08909	2020-09-09

Place(s) of Production:

Final assembly	Address
MaskMakers Sweden AB	Förrådsvägen 23 SE-741-30 Knivsta Sweden

Appendix to EU type-examination certificate

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

Certificate No.: 0200-PPE-08909 version 1

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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	120-30082	RfU 02/075 type-examination of filtering half mask

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 in application form, signed 2020-07-28
- List of applicable EHSR OK, integrated in application form, signed 2020-07-28
- List of materials and sub-suppliers OK, documents product sheet and technical specification
- Description of quality system OK, documents for quality checks in production
- User information and marking OK, markings on the mask, received 2020-08-28
OK, markings on the packaging, received 2020-09-05
OK, instructions for use, received 2020-09-05
- Declaration of innocuousness OK, integrated in application form, signed 2020-07-28

The user information and marking were 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 MM-HM-201, meets the conditions of a temporary and limited approval according to Regulation (EU) 2016/425.

FORCE Certification A/S task No.: 120-30082

Date: 2020-09-09



Kasper Munk Eliassen
Examiner