

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-08901 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:

Applicant: **Respilon Production s.r.o**

For manufacturing the following personal protective equipment:

Type/Description: **Filtering half mask to protect against COVID-19**

Model/Designation: **RespiPro White**

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]: **2020-07-28**

Date of expiry [yyyy-mm-dd]: **2021-01-28**



Søren B. Jensen
Certification Manager



Philippa W. Osted
Examiner

FORCE Certification A/S task No.: **120-29622** / Certificate ID: **08901**

Appendix to EU type-examination certificate

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

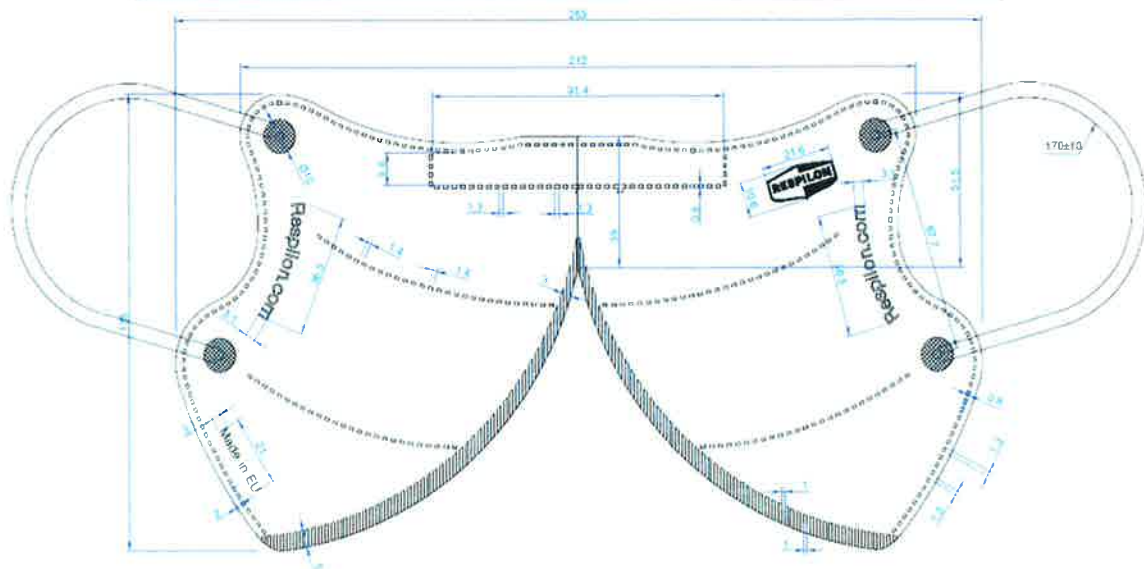
Certificate No.: 0200-PPE-08901 version 1
Issued by FORCE Certification A/S - EU-notified body number 0200

Manufacturer: Respilon Production s.r.o
Prikop 843/4
60200 Brno
Czech Republic

Identification of personal protective equipment:

Type/Description: Filtering half mask to protect against COVID-19
Model/Designation: RespiPro White
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:



RespiPro White

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

Certificate No.: 0200-PPE-08901 version 1
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History:

Issue/change:	Certificate No.:	Certificate ID:	Issue date:
- Original certificate	0200-PPE-08901 version 1	08901	2020-07-28

Place(s) of Production:

Final assembly	Address
Respilon Production s.r.o.	Tehnological Park Brno, building B3, Podnikatelská 2956/6 612 00 Brno

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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	120-29622.01	RfU 02/075 ver. 2 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, "Risk analysis and control productions"
- List of applicable EHSR OK, included in the application
- List of materials and sub-suppliers OK, drawing and bill of materials
- Description of quality system OK, "Risk analysis and control productions"
- User information and marking OK, markings on the mask
OK, instructions for use
OK, markings on packaging
- Declaration of innocuousness OK, included in the application

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 RespiPro White, meets the conditions of a temporary and limited approval according to Regulation (EU) 2016/425.

FORCE Certification A/S task No.: 120-29622
Date: 2020-07-28


Philippa W. Osted
Examiner