

## NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Respilon Production, S.F.O.

Model Tested: RespiPro White

Date Tested: September 29, 2020

These findings pertain to the Respilon Production, S.F.O., model RespiPro White. The packaging for this product indicates that it meets EN149:2001+A1:2009 (the European standard for Respiratory Protective Devices – Filtering Half Masks to Protect Against Particles – Requirements, Testing, Marking).

Ten respirators were submitted for evaluation. The samples were tested using a modified version of NIOSH Standard Test Procedure (STP) TEB-APR-STP-0059. This modified assessment plan can be found [here](#).

No certificate of approval was provided with the samples received; therefore, the authenticity of the claims cannot be validated.

The maximum and minimum filter efficiency was 96.23% and 92.92%, respectively. Six respirators measured more than 95%. Four respirators measured less than 95%.

While the above-listed product classification has similar performance requirements to NIOSH-approved devices, NIOSH does not have knowledge about the sustained manufacturer quality system and product quality control for these products. NIOSH also does not have knowledge about the product's handling and exposures after leaving its manufacturer's control.

In addition, this product is an ear loop design. Currently, there are no NIOSH-approved products with ear loops; NIOSH-approved N95s have head bands. Furthermore, limited assessment of ear loop designs, indicate difficulty achieving a proper fit. While filter efficiency shows how well the filter media performs, users must ensure a proper fit is achieved.

**This assessment is not a part of the NIOSH respirator approval process and will in no way lead to or preclude NIOSH approval through the official approval process.** This assessment was developed as an assessment of the filter efficiency for those respirators represented as certified by an international certification authority, other than NIOSH, to support the availability of respiratory protection to US healthcare workers due to the respirator shortage associated with COVID-19. Only particulate filter efficiency was assessed.

The results provided in this letter are specific to the subset of samples that were provided to NPPTL for evaluation.

These results will be used to update the CDC guidance for [Crisis Capacity Strategies \(during known shortages\)](#).

## Evaluation of International Respirators

**Test:** Modified TEB-APR-STP-0059

**Date Tested:** September 29, 2020

**Report Prepared:** September 29, 2020

**Manufacturer:** Respilon Production, S.F.O.

**Item Tested:** RespiPro White

**Country of Certification:** European (EN149:2001+A1:2009)

Pictures have been added to the end of this report.

Filter	Flow Rate (LPM)	Initial Filter Resistance (mmH <sub>2</sub> O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
1	85	11.9	6.08	6.08	93.92
2	85	17.0	4.76	4.76	95.24
3	85	11.5	4.98	4.98	95.02
4	85	17.4	5.23	5.23	94.77
5	85	11.2	5.81	5.81	94.19
6	85	14.1	4.00	4.00	96.00
7	85	17.3	4.50	4.50	95.50
8	85	10.9	7.08	7.08	92.92
9	85	20.6	4.50	4.50	95.50
10	85	13.6	3.77	3.77	96.23
<b>Minimum Filter Efficiency: 92.92%</b>			<b>Maximum Filter Efficiency: 96.23%</b>		

- The test method utilized in this assessment is not the NIOSH standard test procedure that is used for certification of respirators. Respirators assessed to this modified test plan do not meet the requirements of STP-0059, and therefore cannot be considered equivalent to N95 respirators that were tested to STP-0059.
- Respirators tested may not be representative of all respirators with the same certification mark. NIOSH has no control over suppliers and distributors of respirators certified by other national or international parties.
- This assessment is not a confirmation that it conforms with any or all of its specifications in accordance with its certification mark.
- This assessment was not a part of the NIOSH approval program. These results do not imply nor preclude a future approval through the NIOSH respirator approval program.



# Respi + Pro<sup>®</sup> WHITE

filtration half mask protecting against **COVID-19**

**NANO FIBER**



protection against COVID-19



4.00 g comfortable



perfect facefit



nanofiber filter inside



practical packaging



comes in different sizes

**RESPILON® RespiPro White** is an anti-COVID-19 respirator. Filtration efficiency meets respirator standard RFU 02.075 ver. 2 ([www.ppe-rfu.eu/app/uploads/sites/10/2020/04/RFU-02.075\\_01\\_Regulation.pdf](http://www.ppe-rfu.eu/app/uploads/sites/10/2020/04/RFU-02.075_01_Regulation.pdf)) Intended to be used for max. one workshift.  
**Certification authority:** FORCE Certification A/S, Park alle 345, 2605 Brøndby, Denmark, NB 0200  
**Shelf life:** 5 years from the date of manufacture on the packaging  
**Storage:** store in original packaging, away from contaminated areas, dust, sunlight, extreme temperatures, excessive moisture and damaging chemicals  
**Storage conditions:** temperature from -10°C to +40 °C, max. relative humidity < 80 %  
**Usage:** do not use in oxygen deficient atmospheres; do not use around open flame

This filtering half mask is manufactured for COVID-19 protection only. As requested by World Health Organization recommendations, for this specific use, the nominal protection factor given by this filtering half mask is the same as the FFP2 nominal protection factor defined in EN 149:2001+A1:2009. 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.

### Warning

Do not lend your respirator to others. Store the respirator in a cool, dry place, out of direct sunlight. To achieve the best possible fit, do not wear make-up. Hair and/or facial hair may decrease the respirator's adhesion, and thus reduce its protective properties. Do not use as protection from gases, fumes and volatile substances. Children can only use the respirator under the supervision of their parents/guardians. Not recommended for ages below 2.5 years. Stop using the face mask immediately if it is causing you any discomfort.

**RESPILON® RespiPro White** je respirátor sloužící k ochraně proti COVID-19. Účinnost filtrace odpovídá standardu pro respirátory RFU 02.075 ver. 2 ([www.ppe-rfu.eu/app/uploads/sites/10/2020/04/RFU-02.075\\_01\\_Regulation.pdf](http://www.ppe-rfu.eu/app/uploads/sites/10/2020/04/RFU-02.075_01_Regulation.pdf)) Určeno pro max. jednu pracovní směnu.  
**Certifikační autorita:** FORCE Certification A/S, Park alle 345, 2605 Brøndby, Denmark, NB 0200  
**Skladovatelnost:** 5 let od data výroby (v neporušeném obalu)  
**Skladování:** uchovávejte v původním obalu na místě bez kontaminace, prachu, přímého slunečního světla, extrémních teplot, nadměrné vlhkosti a chemikálií  
**Podmínky skladování:** teplota od -10°C do +40°C, max. relativní vlhkost < 80 %  
**Užití:** nepoužívat v ovzduší s nižší koncentrací kyslíku; nepoužívat v blízkosti otevřeného ohně

Tato filtrační polomaska je vyráběna pouze za účelem ochrany proti nemoci COVID-19. Jak pro tento konkrétní účel vyžadují doporučení Světové zdravotnické organizace, je jmenovitý filtrační koeficient této filtrační polomasky stejný jako jmenovitý filtrační koeficient FFP2 stanovený EN 149:2001+A1:2009. Tato filtrační polomaska není filtrační polomaskou pro všeobecné použití a není určena k jinému účelu než k ochraně proti nemoci COVID-19.

### Varování

Nepůjčujte svůj respirátor dalším osobám. Skladujte na chladném a suchém místě mimo přímé slunce. Pro maximální přiléhavost masky vyloučte make-up. Vlasy a/nebo vousy mohou způsobit nižší přiléhavost respirátoru, a tím snížit jeho ochranný účinek. Nepoužívejte proti plynům, výparům a těkavým látkám. Děti smějí respirátor používat vyhradně pod dohledem rodičů. Nedoporučujeme používat respirátor dětem mladším 2,5 roku. V případě jakýchkoliv obtíží přestaňte respirátor ihned používat.

### Application

- Open the package, take out the the filtration half mask and unfold it.
- Place the filtration half mask on the root of your nose and hold it with one hand.
- Use your other hand to pull the ear loops behind your ears.
- Press the nose clip firmly around the root of your nose.
- Hook the plastic buckle around both ear loops and pull it over the back of your head.



LIFE'S WORTH IT

Expiration date: 08/2025

Datum expirace:

Lot number: 2020  
 Šarže:

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Designed in Europe | Vytvunuto v Evropě  
 EU declaration of conformity: [www.respilon.com](http://www.respilon.com)



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