NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Respilon Production s.r.o.
Model Tested: RespiPro VK (Type: RPVK-L/M/S-000)
Date Tested: December 14, 2020

These findings pertain to the Respilon Production s.r.o., model RespiPro VK (Type: RPVK-L/M/S-000). 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 96.66% and 95.06%, respectively. All ten respirators measured more 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

NPPTL
National Personal Protective Technology Laboratory

Test: Modified TEB-APR-STP-0059

Date Tested: December 14, 2020

Report Prepared: December 14, 2020

Manufacturer: Respilon Production s.r.o.

Item Tested: RespiPro VK (Type: RPVK-L/M/S-000)

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_2O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
1	85	14.2	3.56	3.56	96.44
2	85	13.1	4.92	4.92	95.08
3	85	18.7	4.58	4.58	95.42
4	85	23.3	4.94	4.94	95.06
5	85	17.6	3.34	3.34	96.66
6	85	15.7	4.87	4.87	95.13
7	85	18.2	4.94	4.94	95.06
8	85	13.5	3.86	3.86	96.14
9	85	21.9	4.41	4.41	95.59
10	85	14.6	4.08	4.08	95.92
Minimum Filter Efficiency: 95.06%			**Maximum Filter Efficiency: 96.66%**		

- 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.


VK
Respi Pro®
Self-Sterilizing Mask Enriched with Accelerated Copper Oxide
RESPILON
Respilon.com
RESPILON


RESPILON helps people to live better
and healthier lives since 2013.
L
size
3.7g INCREDIBLY LIGHT
10
pcs
RespiPro® VK je respirátor určený výhradně k ochraně proti COVID-19. Účinnost filtrace odpovídá standardu pro respirátory RFU 02.075 ver. 2.
RespiPro® VK filtering half mask is to be used for COVID-19 protection only. Filtration efficiency meets respirator standard RFU 02.075 ver. 2.
Certifikační autorita | Certification authority: FORCE Certification A/S, Park alle 345, 2605 Brøndby, Denmark, NB 0200
EU prohlášení o shodě | EU declaration of conformity: www.respilon.com
Respilon Production s.r.o.
Příkop 843/4, 602 00 Brno,
Czech Republic, Europe
+420 530 332 163
www.respilon.com
Date of manufacture: see packaging
Datum výroby: viz obal
Lot number: see packaging | Šarže: viz obal
23112020
202011
CE 0200
7
PP
FSC
www.fsc.org
MIX
Board from responsible sources
FSC® C117597
8 595190 531578


VK Respi Pro®
Self-sterilizing filtration half mask
protecting against COVID-19


VK Respi Pro®
Samosterilizační respirátor
k ochraně před nemocí COVID-19


RESPILON®

EN

Product Information

RespiPro® VK (type: RPVK-L/M/S-000) is an anti-COVID-19 half mask. 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) The half mask has self-sterilizing properties preventing cross-contamination. The respirator works on a double barrier principle – its nanofiber membrane immediately blocks out 99.7–99.9 % of viruses and accelerated copper oxide subsequently ensures a decontamination effect. A renown American laboratory Nelson Labs, who have tested the accelerated copper oxide, have confirmed it to deactivate 99.7 % of the viruses that cause COVID-19. Intended to be used cumulatively for max. 30 h (e.g. 5 h a day for 6 days).

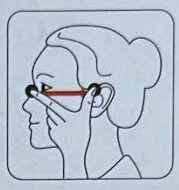
Certification authority: FORCE Certification A/S, Park alle 345, 2605 Brøndby, Denmark, NB 0200
Shelf life: 5 years from the date of manufacture on the packaging
Storage: store in original packaging in a cool, dry place
Storage conditions: -10 °C to +40 °C, max. relat. humidity < 80 %
Filter: RESPILON® RFT blocks out 99.7–99.9 % of viruses, tested by Nelson Labs (VFE)

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

Hair and/or facial hair may decrease the half mask's face fit, and thus reduce its protective properties. Do not use as protection from gases and VOCs. Not recommended for ages below 2.5 years. If it is causing you any discomfort, breathing complications, or a rash stop using the half mask as soon as possible.

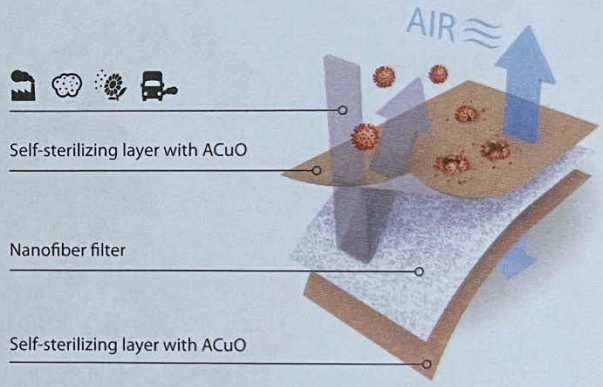
Select Proper Size



1. Measure the distance (in cm) shown in the picture
2. Compare the measured distance in cm with the size coverage chart

Size Coverage:
S < 9 cm | M < 12 cm | L < 16 cm

RESPILON® VK Membrane



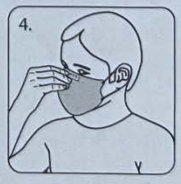
EU declaration of conformity www.respilon.com
Manufactured by RESPILON in EU | Designed by RESPILON in EU

Application

Sanitize your hands before opening the package, take out the half mask and unfold it.

Place the 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.

Join both ear loops with the plastic hook over the back of your head.


Respilon.com
Made in EU
RESPILON
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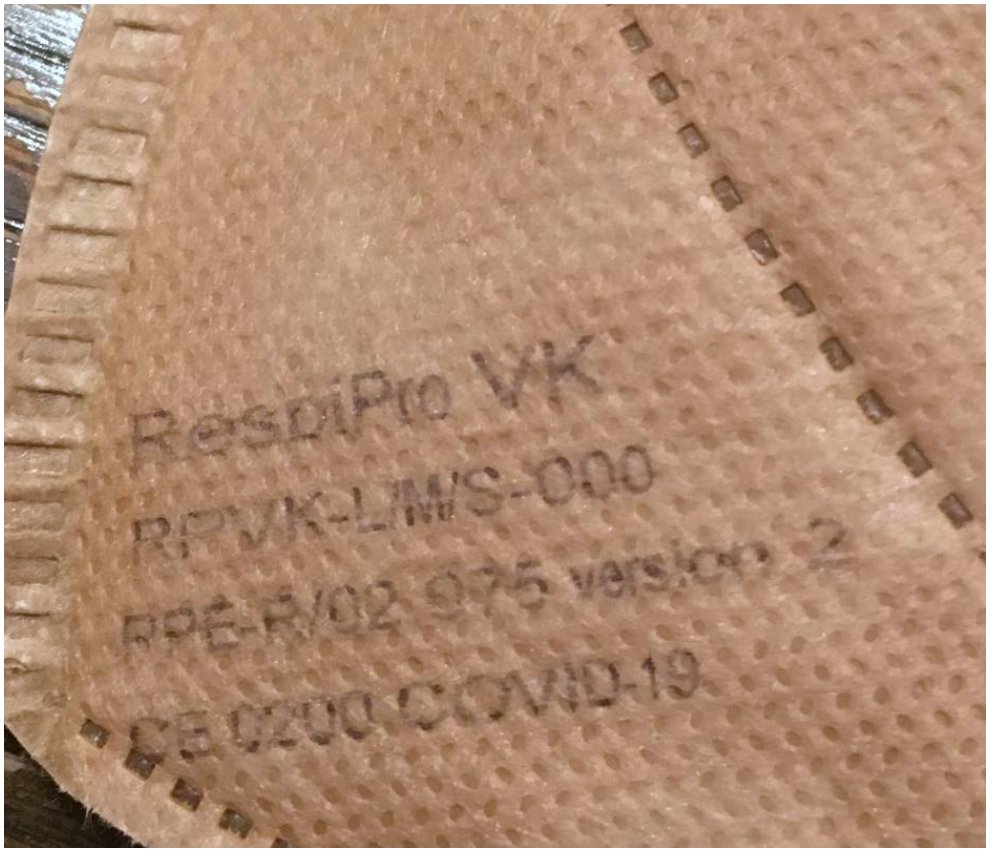
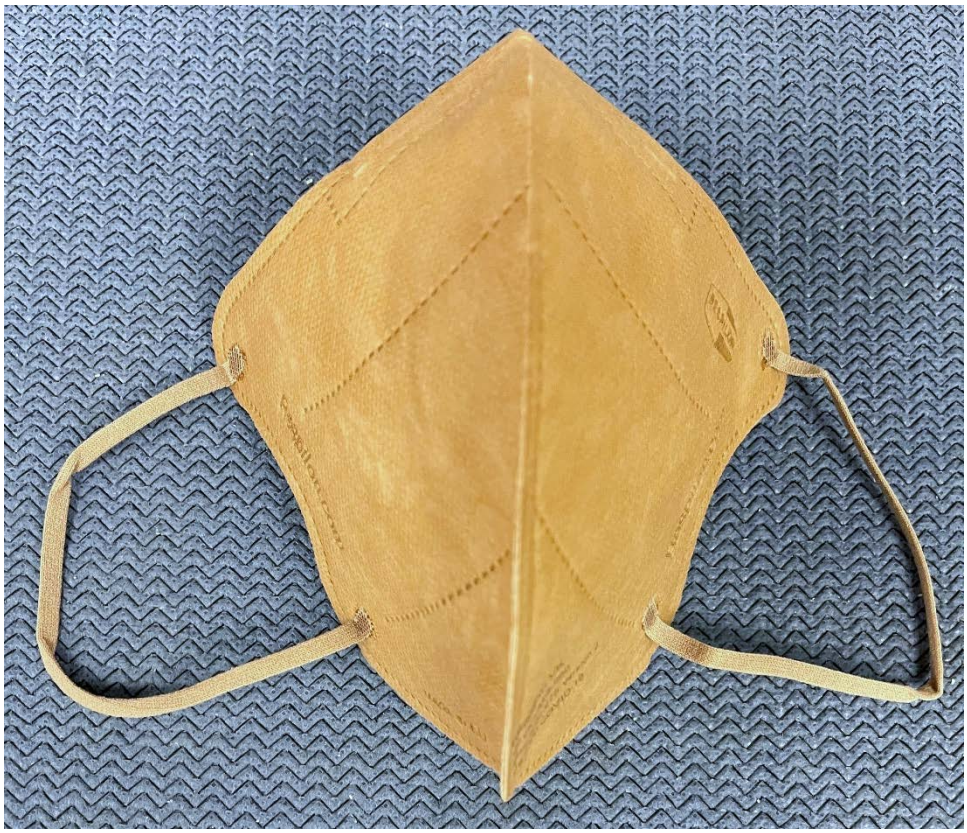

ResDiPro VK
RPVK-LIWS-000
RPE-R/02.975 version 2
CE 0200 COVID-19



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