

NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Xiamen Blue Star Enterprise Co., Ltd.

Model Tested: RespiPro Carbon FFP2 Nanofiber Respirator

Date Tested: September 15, 2020

These findings pertain to the Xiamen Blue Star Enterprise Co., Ltd., model RespiPro Carbon FFP2 Nanofiber Respirator. The packaging for this product indicates that it meets GB2626-2006 (the Chinese standard for Respiratory Protective Equipment – Non-Powered Air-Purifying Particle Respirator). The packaging and labeling indicate that it also 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 98.94% and 98.28%, respectively. All 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

Test: Modified TEB-APR-STP-0059

Date Tested: September 15, 2020

Report Prepared: September 15, 2020

Manufacturer: Xiamen Blue Star Enterprise Co., Ltd.

Item Tested: RespiPro Carbon FFP2 Nanofiber Respirator

Country of Certification: China (GB2626-2006), European (EN149:2001+A1:2009)

Pictures have been added to the end of this report.

Filter	Flow Rate (LPM)	Initial Filter Resistance (mmH ₂ O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
1	85	14.5	1.62	1.62	98.38
2	85	13.8	1.60	1.60	98.40
3	85	14.0	1.72	1.72	98.28
4	85	13.5	1.57	1.57	98.43
5	85	14.1	1.27	1.27	98.73
6	85	11.2	1.53	1.53	98.47
7	85	14.5	1.20	1.20	98.80
8	85	16.8	1.65	1.65	98.35
9	85	11.1	1.60	1.60	98.40
10	85	14.0	1.06	1.06	98.94
Minimum Filter Efficiency: 98.28%			Maximum Filter Efficiency: 98.94%		

- 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.



Distributor



Producer
 RESPILON Group s.r.o.
 Brno, Czech Republic
 phone: +420 530 332 163
 web: www.respilon.com

RESPILON filtration halfmask

RESPILON® Filtration Halfmask is a FFP2 NR filtration halfmask. It fulfils standards EN 149:2001+A1:2009 and GB2626-2006 KN95. -Intended to be used for max. one workshift.

Shelf life: 7 years from the date of production on the package

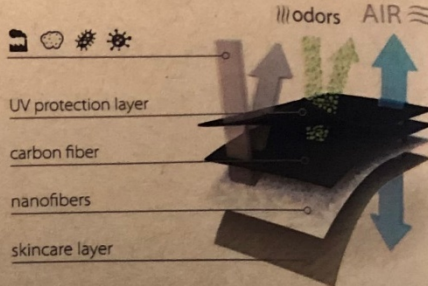
Primary purpose: protection of respiratory tract against aerosols, solid and liquid particles and odors.

Storage: store in original packaging, away from contaminated areas, dust, sunlight, extreme temperatures, excessive moisture, and damaging chemicals.

Storage conditions: temperature from -20 °C to +40 °C, max. relative humidity: <95 %

Usage: not for use in atmospheres containing less than 19.5 % oxygen. Only to be used for healthcare protection at workplace. Not to be used in areas with open flames.

RESPILON® filter



Warning

Please, read the instructions before putting the half mask on. Stop using the half mask immediately if it's causing you any discomfort. Facial hair and hair can affect the face fit of the half mask and reduce its protective qualities. Don't lend your half mask to anyone. Re-use or extended use (beyond 5 hours) may lead to infection or cross-contamination. Do not use the half mask when concentrations/contaminants are unknown or immediately dangerous for life or health. When to replace: Go to a clean, safe area away from other people, and replace your half mask if it is damaged, has been splashed or sprayed with body fluids, or if it becomes harder to breathe through.

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: M size ≤ 12 cm
 L size ≤ 16 cm

Application



1. Open the package, take out the filtration half mask and unfold it.



2. Place the filtration half mask on the root of your nose and hold it with one hand.



3. Use your other hand to pull the ear loops behind your ears.

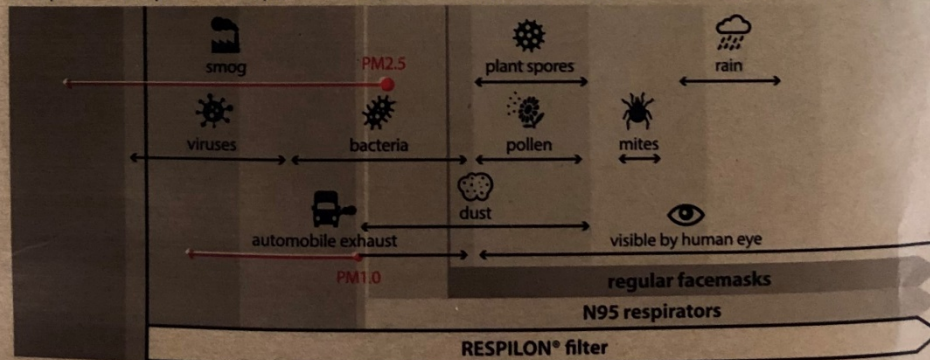


4. Press the nose clip firmly around the root of your nose.



5. Hook the plastic buckle around both ear loops and pull it over the back of your head.

0.001 µm 0.01 µm 0.1 µm 1.0 µm 10 µm 100 µm 1000 µm 10,000 µm



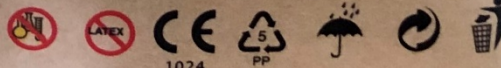
Complies with EU regulation 2016/425 | controlled by VÚBP, DS 1024 Jeruzalémská 1283/9, 110 00 Praha 1, Czech Republic
 Declaration of conformity available on: <http://www.respilon.com/prohlaseniashode4-200-4-4001FFP2NR>



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Designed by
 RESPILON® in EU,
 assembled in PRC

www.r-masks.com



Manufacturer: Xiamen Blue Star Enterprise Co., Ltd.
 Manufacturing Date 6/25/2020

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