

## NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Shandong Haidike Medical Products Co., Ltd.

Model Tested: N95-V1 Medical Respirator

Date Tested: January 19, 2021

These findings pertain to the Shandong Haidike Medical Products Co., Ltd., N95-V1 Medical Respirator. The packaging for these respirators indicates they meet GB19083-2010 (the Chinese standard for Technical Requirements for Protective Face Mask for Medical Use).

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 97.49% and 95.14%, 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.

This product has head bands/straps. 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:** January 19, 2021

**Report Prepared:** January 19, 2021

**Manufacturer:** Shandong Haidike Medical Products Co., Ltd.

**Item Tested:** N95-V1 Medical Respirator

**Country of Certification:** China (GB19083-2010)

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	19.5	2.51	2.51	97.49
2	85	22.9	2.73	2.73	97.27
3	85	27.0	4.86	4.86	95.14
4	85	30.2	3.96	3.96	96.04
5	85	26.3	2.68	2.68	97.32
6	85	28.6	3.45	3.45	96.55
7	85	20.8	2.51	2.51	97.49
8	85	33.5	4.20	4.20	95.80
9	85	21.9	2.84	2.84	97.16
10	85	27.0	3.91	3.92	96.08
<b>Minimum Filter Efficiency: 95.14</b>			<b>Maximum Filter Efficiency: 97.49</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.

# well before

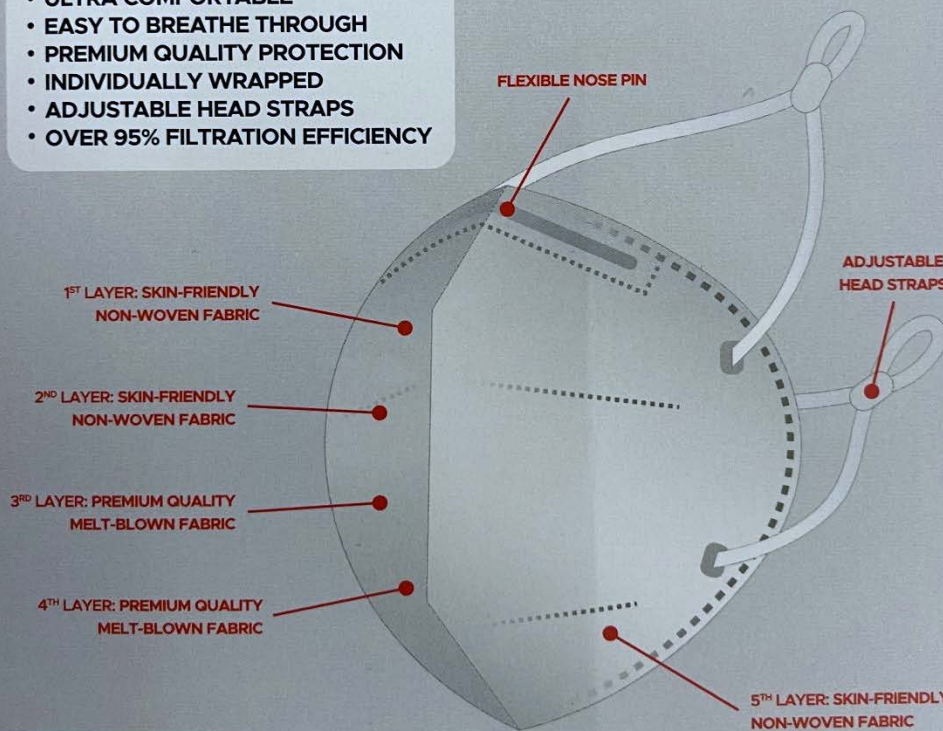
formerly **H  PPE**  
SUPPLY

## **N95-V1** MEDICAL RESPIRATOR PROTECTIVE RESPIRATOR FOR MEDICAL USE

FOLDING TYPE MEETS GB19083-2010 STANDARD FILTRATION EFFICIENCY  $\geq$  95%

- 5 LAYERS OF PROTECTION
- ULTRA COMFORTABLE
- EASY TO BREATHE THROUGH
- PREMIUM QUALITY PROTECTION
- INDIVIDUALLY WRAPPED
- ADJUSTABLE HEAD STRAPS
- OVER 95% FILTRATION EFFICIENCY

STERILE EO STERILE



**5-LAYERS  
OF PROTECTION**

[www.wellbefore.com](http://www.wellbefore.com)



5 LAYERS



SOFT



NON-IRRITATING



ODORLESS



95% FILTRATION

**10 PCS**  
INDIVIDUALLY  
WRAPPED

MEETS GB19083-2010 STANDARD | PROTECTIVE RESPIRATOR FOR MEDICAL USE | FILTRATION EFFICIENCY  $\geq$  95%

# well before

formerly **H  PPE**  
SUPPLY

## **N95-V1** MEDICAL RESPIRATOR PROTECTIVE RESPIRATOR FOR MEDICAL USE

**FOLDING TYPE    MEETS GB19083-2010 STANDARD    FILTRATION EFFICIENCY  $\geq$  95%**

**Performance:**

1. The product should be clean, free of dirt, odor and discoloration. In addition, the product should not be damaged, cracked or show any deformations.
2. Filtration efficiency  $\geq$  95%

**Contraindications:**

This product should not be used by individuals who have allergic reactions to materials.

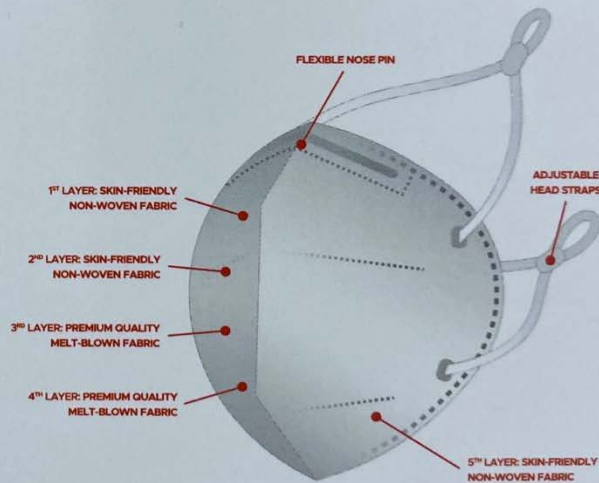
**Warnings:**

1. This product is intended for single-use only. Discard after use.
2. If the package is damaged, discard the product.

**Storage and transportation conditions:**

This product should be stored in environments that are cool, dry, clean, dark, free of corrosive gases, and well-ventilated. It should be transported in a clean and hygienic manner, and it should be isolated from fire sources.

**STERILE EO    STERILE**



**Brand:** wellbefore

**Product Name:** N95-V1 Medical Respirator

**Layers:** 1. Non-Woven Fabric

2. Non-Woven Fabric

3. Melt-Blown Fabric

4. Melt-Blown Fabric

5. Non-Woven Fabric

**Implementation Standard:** GB 19083-2010

**Shandong Haidike Medical Products Co., Ltd.**

**Address:** Tianfu Road, Dongcheng District, Shan County, Heze City, Shandong Province, China

[www.wellbefore.com](http://www.wellbefore.com)

**LOT:** 2021102  
**M:** 2020-11-02  
**D:** 2021-10-01



MADE IN CHINA



DESIGNED IN TEXAS

**USE INSTRUCTIONS:**

**1**  
Unfold the mask.



**2**  
Put a mask on your face and wrap the head straps around your head.



**3**  
Tighten the adjustable knobs on a head straps to ensure tight and comfortable fit.



**4**  
Bend the nose pin to ensure good fit on the nose.



**WHITE**

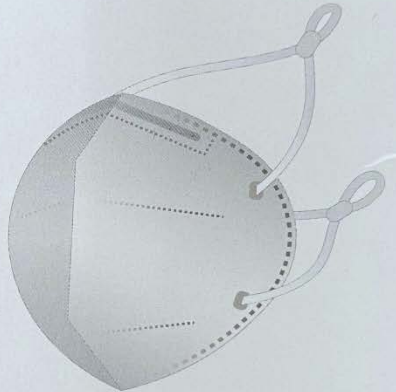
**10 PCS**  
INDIVIDUALLY WRAPPED

**N95-V1**


**MEDICAL RESPIRATOR**


PROTECTIVE RESPIRATOR FOR MEDICAL USE



FOLDING TYPE  
MEETS GB19083-2010 STANDARD  
FILTRATION EFFICIENCY ≥ 95%




**STERILE | EO | STERILE**

 No reuse

 Consult instructions for use

 Caution  Keep dry

 Keep away from sunlight

**10 PCS**  
INDIVIDUALLY WRAPPED



# wellbefore

formerly **HOPPE** SUPPLY

## N95-V1 MEDICAL RESPIRATOR

PROTECTIVE RESPIRATOR FOR MEDICAL USE

FOLDING TYPE MEETS GB19083-2010 STANDARD FILTRATION EFFICIENCY > 95%

STERILE EO STERILE

- Keep away from sunlight
- Consult instructions for use
- Caution
- No reuse
- Keep dry

1<sup>st</sup> LAYER: SKIN-FRIENDLY NON-WOVEN FABRIC

2<sup>nd</sup> LAYER: SKIN-FRIENDLY NON-WOVEN FABRIC

3<sup>rd</sup> LAYER: PREMIUM QUALITY MELT-BLOWN FABRIC

4<sup>th</sup> LAYER: PREMIUM QUALITY MELT-BLOWN FABRIC

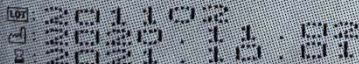
5<sup>th</sup> LAYER: SKIN-FRIENDLY NON-WOVEN FABRIC

FLEXIBLE NOSE PIN

ADJUSTABLE HEAD STRAPS

Shandong Haidike Medical Products Co., Ltd.  
Address: Tianfu Road, Dongcheng District, Shan County, Heze City, Shandong Province, China

Brand: wellbefore  
Product Name: N95-V1 Medical Respirator  
Layers: 1. Non-Woven Fabric  
2. Non-Woven Fabric  
3. Melt-Blown Fabric  
4. Melt-Blown Fabric  
5. Non-Woven Fabric  
Implementation Standard: GB 19083-2010



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### Performance:

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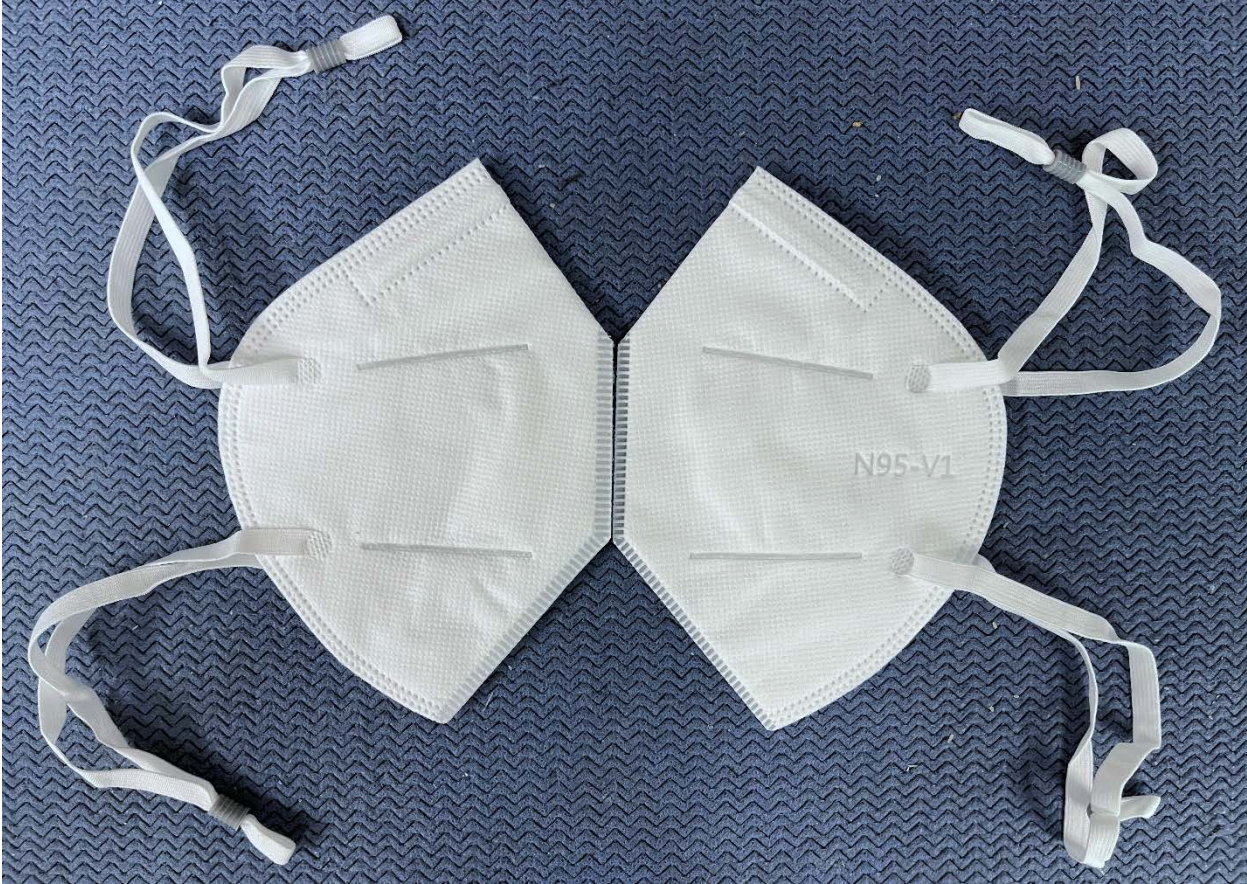
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5-LAYERS OF PROTECTION

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