

NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Hunan Wondo Medical Supplies Co., Ltd.

Model Tested: Medical Protective Mask (Non-Sterile) - Foldable Type

Date Tested: June 17, 2020

These findings pertain to the Hunan Wondo Medical Supplies Co., Ltd., Medical Protective Mask (Non-Sterile) - Foldable Type. 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 97.24% and 96.07%, 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 respirator's 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: June 17, 2020

Report Prepared: June 17, 2020

Manufacturer: Hunan Wondo Medical Supplies Co., Ltd.

Item Tested: Medical Protective Mask (Non-Sterile) - Foldable Type

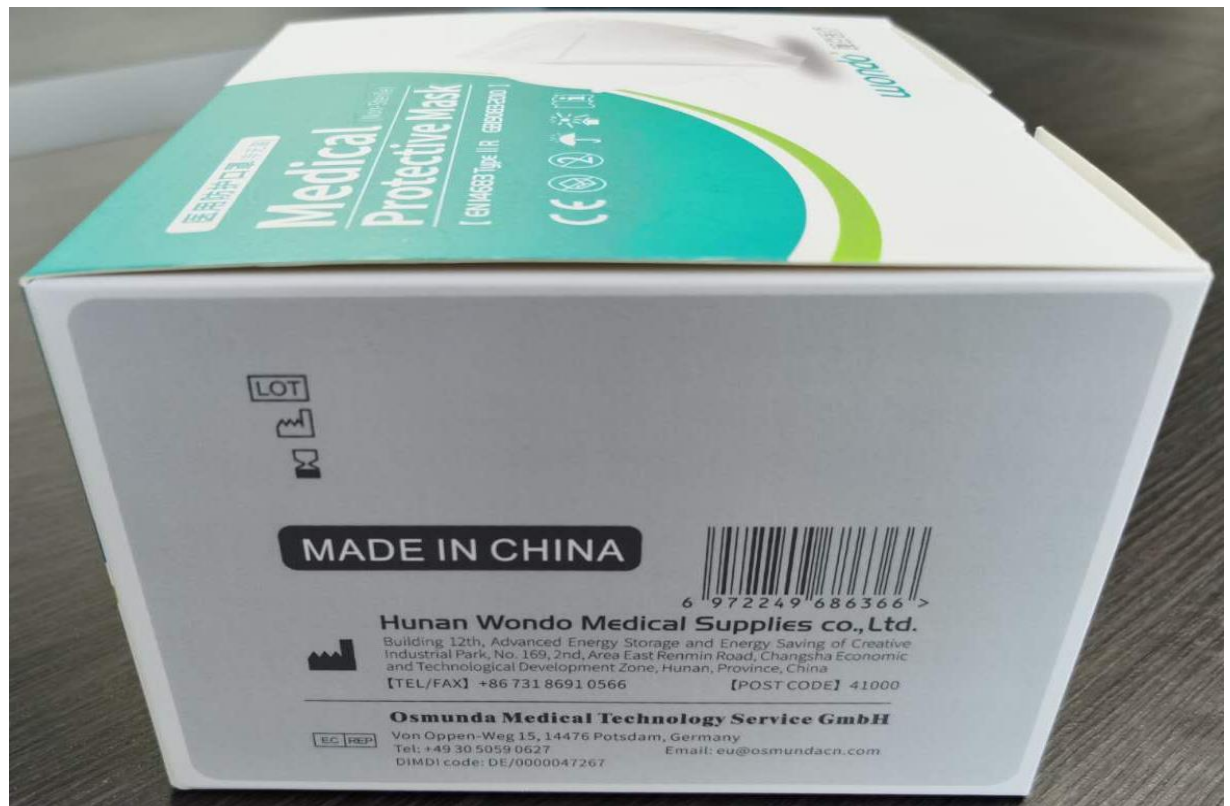
Country of Certification: China (GB19083-2010)

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	12.1	2.90	2.90	97.10
2	85	12.0	2.76	2.76	97.24
3	85	12.7	3.31	3.31	96.69
4	85	11.5	3.29	3.29	96.71
5	85	12.0	3.39	3.39	96.61
6	85	13.3	3.14	3.14	96.86
7	85	12.3	3.04	3.04	96.96
8	85	11.5	3.31	3.31	96.69
9	85	16.4	3.93	3.93	96.07
10	85	14.0	3.36	3.36	96.64
Minimum Filter Efficiency: 96.07			Maximum Filter Efficiency: 97.24		

- 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.

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[Product name] Medical Protective Mask (Non-Sterile)

[Model] Foldable type

[Scope of application]

Medical protective mask (non-sterile) is suitable for the basic protection of medical staff and related workers under the environment with the risk of airborne respiratory infections. It can filter the particulate matter in the air and block the droplet, the blood, the body fluid, the secretions and so on. The medical protective mask cannot use in the isolation intensive care unit (room) and other places with strict control of microbial indicators.

[Product Performance]

The product meets the requirements of EN 14683-2019+AC: 2019 Type II R. The main parameters of the product are listed in the following:

Bacterial filtration efficiency (BFE), $\geq 98\%$

Splash resistance pressure, ≥ 16.0 kPa

Differential pressure, < 60 Pa/cm²

Microbial cleanliness, ≤ 30 cfu/g

[Structure and Components] Medical protective mask (Non-Sterile) consists of mask body, nose clip and mask belt. The material of surface layer and bottom layer is polypropylene spun-bonded non-woven fabric. The material of middle filter layer is polypropylene melt-blown fabric. The material of nose clip is flexible polypropylene or aluminum which is interchangeable. The material of mask belt is spandex.

[Model and Specifications] size: 15.2 cm × 10.5 cm, deviation $\pm 5\%$.

[Wearing Instructions]

1. Hold the mask belts in each hand so that the nose clip is located on the bridge of the nose.
2. Place the fingers of both hands in the middle of the nose clip. Press the nose clip inward and meanwhile move the fingertips along the nose clip

to the two sides until the clip is fully pressed into the shape of the bridge of the nose. Using only one hand to press the nose clip may affect the tightness of the mask.

3. Check air tightness when wearing each time: cover the mask with hands and exhale, readjust the nose clip if there is gas coming out from the nose clip. Otherwise, do not wear this product to enter a dangerous area. Seek help from a supervisor or manufacturer.

[Manufacture Date] Refer the spray code on package

[Service Life] Three years

[Contraindication] None

[Warnings]

1. The mask can only be used once. Do not re-use or wash this product.
2. Pulling the mask belt too hard may cause breaking.
3. Do not reuse the product after using it in known or suspected contaminated areas. Replace the mask immediately after it is contaminated with the patient's blood or body fluids.
4. Stop using the product in case of itching, earache or other symptoms appears.
5. Make sure the surface of the contact skin treated before using this product if there is any injury in your lips, nose or other skin surface in contact with this product.

[Caution]

1. Keep away from heat and fire.
2. It is strictly prohibited to use this product in special environment including coal gas or harmful dust.

[Storage Conditions]

It is recommended to store in dry, ventilated, non-corrosive environment. Keep away from fire and inflammable. Avoid heavy load, direct sunlight, rain and snow.





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The product meets the requirements of EN 14683-2019+AC: 2019 Type II R.

The main parameters of the product are listed in the following:

Bacterial filtration efficiency (BFE), $\geq 98\%$

Splash resistance pressure, ≥ 16.0 kPa

Differential pressure, < 90 Pa/cm²

Microbial cleanliness, ≤ 30 cfu/g

[Structure and Components] Medical protective mask (Non-Sterile) consists of mask body, nose clip and mask belt. The material of surface layer and bottom layer is polypropylene spun-bonded non-woven fabric. The material of middle filter layer is polypropylene melt-blown fabric. The material of nose clip is flexible polypropylene or a luminum which is interchangeable. The material of mask belt is spandex.

[Model and Specifications] size: 15.2 cm \times 10.5 cm, deviation $\pm 9\%$.

[Wearing Instructions]

1. Hold the mask belts in each hand so that the nose clip is located on the bridge of the nose.
2. Place the fingers of both hands in the middle of the nose clip. Press the nose clip inward and meanwhile move the fingertips along the nose clip

to the two sides until the clip is fully pressed into the shape of the bridge of the nose. Using only one hand to press the nose clip may affect the tightness of the mask.

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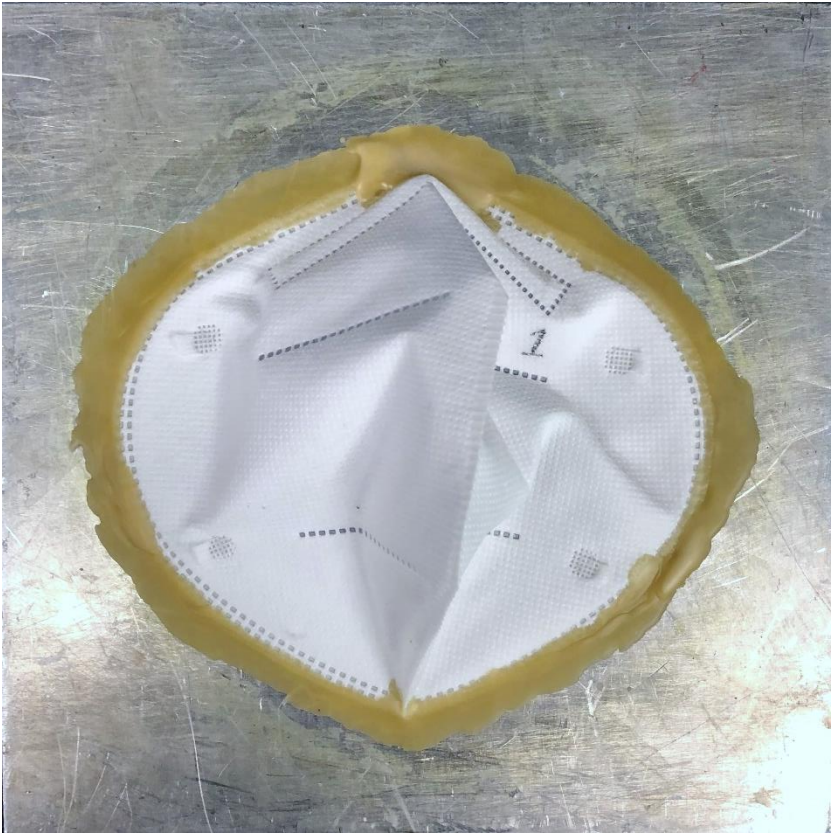
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