

## NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Dongguan Xianda Medical Equipment Co., Ltd.  
Model Tested: KN95 Protective Mask  
Date Tested: April 15, 2020

These findings pertain to the Dongguan Xianda Medical Equipment Co., Ltd., model KN95 Protective Mask. The labeling for these respirators indicate they meet GB2626-2006 (the Chinese standard for Respiratory Protective Equipment – Non-Powered Air-Purifying Particle Respirator) and 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 35.00% and 24.10%, respectively. All ten respirators measured less than 95%.

While the above-listed product classifications have 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 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:** April 15, 2020

**Report Prepared:** April 16, 2020

Pictures have been added to the end of this report.

**Manufacturer:** Dongguan Xianda Medical Equipment Co., Ltd.

**Item Tested:** KN95 Protective Mask

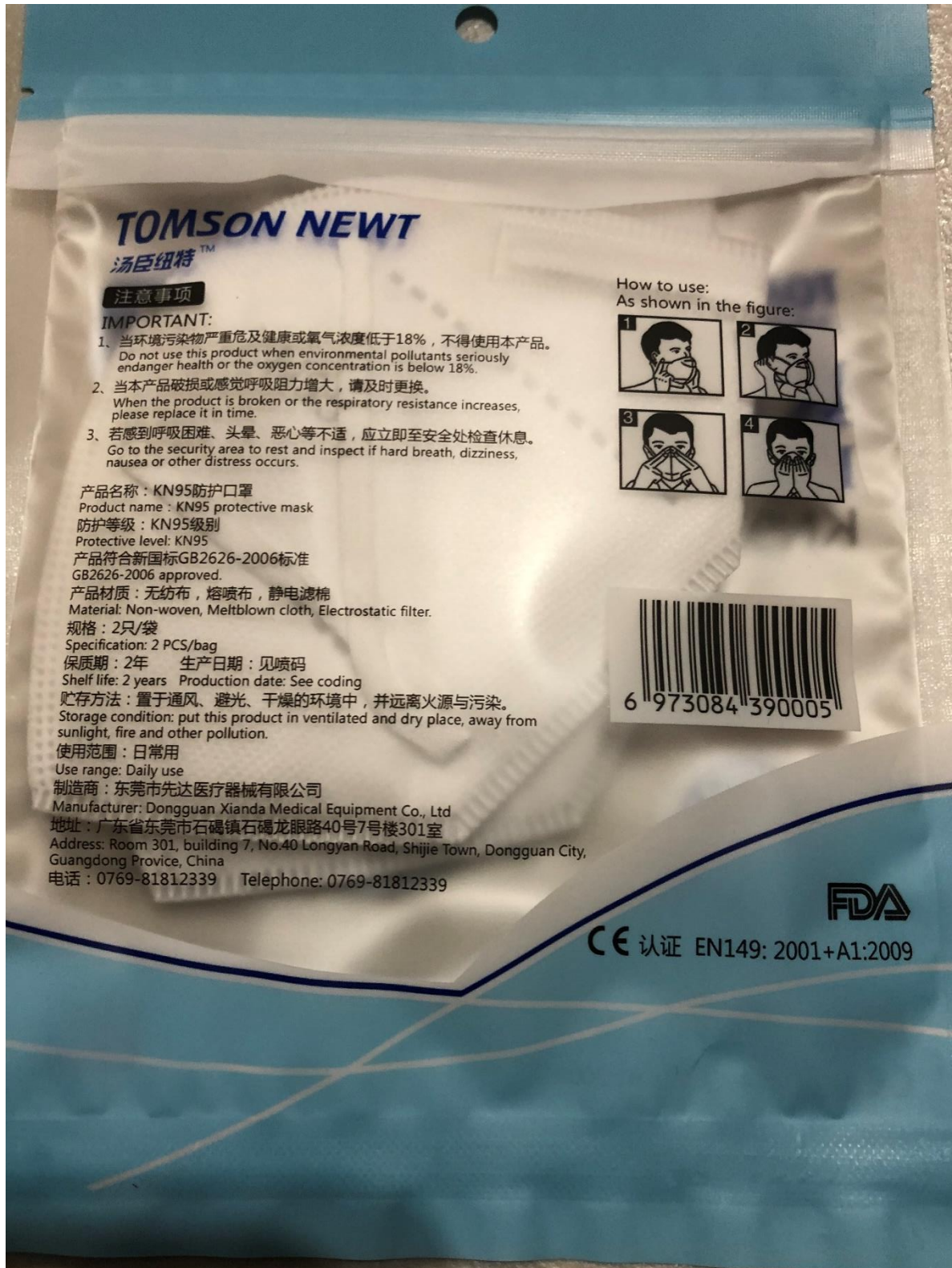
**Country of Certification:** China (Chinese Standard GB2626, European Standard EN149)

Filter	Flow Rate (Lpm)	Initial Filter Resistance (mmH <sub>2</sub> O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency
1	85	3.9	74.4	75.9	24.1
2	85	5.1	71.0	72.0	28.0
3	85	5.0	71.4	71.4	28.6
4	85	4.5	73.1	73.6	26.4
5	85	5.9	71.7	71.7	28.3
6	85	5.1	71.56	71.64	28.36
7	85	4.7	71.7	73.3	26.7
8	85	5.1	64.4	65.0	35.0
9	85	5.0	68.8	68.8	31.2
10	85	5.0	72.9	74.0	26.0
<b>Minimum Filter Efficiency: 24.10</b>			<b>Maximum Filter Efficiency: 35.00</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.







**TOMSON NEWT**

汤臣纽特™

**注意事项**

**IMPORTANT:**

1. 当环境污染物严重危及健康或氧气浓度低于18%，不得使用本产品。  
Do not use this product when environmental pollutants seriously endanger health or the oxygen concentration is below 18%.
2. 当本产品破损或感觉呼吸阻力增大，请及时更换。  
When the product is broken or the respiratory resistance increases, please replace it in time.
3. 若感到呼吸困难、头晕、恶心等不适，应立即至安全处检查休息。  
Go to the security area to rest and inspect if hard breath, dizziness, nausea or other distress occurs.

产品名称：KN95防护口罩

Product name: KN95 protective mask

防护等级：KN95级别

Protective level: KN95

产品符合新国标GB2626-2006标准

GB2626-2006 approved.

产品材质：无纺布，熔喷布，静电滤棉

Material: Non-woven, Meltblown cloth, Electrostatic filter.

规格：2只/袋

Specification: 2 PCS/bag

保质期：2年 生产日期：见喷码

Shelf life: 2 years Production date: See coding

贮存方法：置于通风、避光、干燥的环境中，并远离火源与污染。

Storage condition: put this product in ventilated and dry place, away from sunlight, fire and other pollution.

使用范围：日常用

Use range: Daily use

制造商：东莞市先达医疗器械有限公司

Manufacturer: Dongguan Xianda Medical Equipment Co., Ltd

地址：广东省东莞市石碣镇石碣龙眼路40号7号楼301室

Address: Room 301, building 7, No.40 Longyan Road, Shijie Town, Dongguan City, Guangdong Province, China

电话：0769-81812339 Telephone: 0769-81812339

How to use:  
As shown in the figure:



**FDA**

CE 认证 EN149: 2001+A1:2009

NPPTL COVID-19 Response: International Respirator Assessment





NPPTL COVID-19 Response: International Respirator Assessment



NPPTL COVID-19 Response: International Respirator Assessment

