

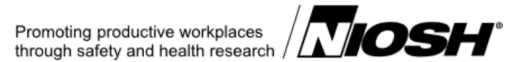
Source: CDC

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<https://www.cdc.gov/niosh/npptl/respirators/testing/NonNIOSHresults.html>

For particulate filter efficiency test results using the original **NIOSH** Standard Test Procedure **TEB-APR-STP-0059** "Determination of Particulate Filter Efficiency Level for N95 Series Filters against Solid Particulates for Non-Powered, Air-Purifying Respirators Standard Testing Procedure Revision 3.2, 13 December 2019", please refer to our document [Chengde Respirator NIOSH Precertification ICS Test Report No. T148601-01-1 Issue 1.pdf](#).

cdc.gov/niosh/npptl/respirators/testing/NonNIOSHresults.html



# NPPTL Respirator Assessments to Support the COVID-19 Response

Updated October 29, 2020

## International Assessment Results – Not NIOSH- approved

NPPTL has completed International Assessments for the products listed below.

### Respirator Assessment Results

Manufacturer	Model Number/Product Line	International Standard	Filtration Efficiency (%)		Test Report
			Maximum	Minimum	
3M	9502+	GB2626	98.56	98.24	<a href="#">2020-168.1</a> 
3M	9502+	GB2626	99.17	97.27	<a href="#">2020-176.1</a> 
		/// This gap is intentional. ///			
Chengde Technology Co., Ltd.	KN95 Respirator Protective Mask	EN149, GB2626	99.54	95.11	<a href="#">2020-160.1</a> 

The **National Personal Protective Technology Laboratory (NPPTL)** is a Division of the **National Institute for Occupational Safety and Health (NIOSH)**. NPPTL prevents work-related injury, illness, and death by advancing the state of knowledge and application of personal protective technologies (PPT). NPPTL supports more than 20 million U.S. workers who rely on this equipment (e.g., respirators, clothing, gowns, gloves, eye protection and other types of protective gear) to keep them safe from on-the-job hazards.



NPPTL conducts laboratory and field research, surveillance, standards development, interventions, and conformity assessment activities. This work includes

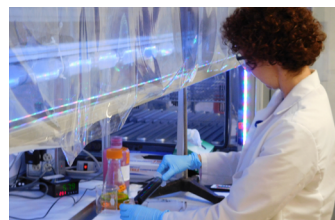
the respirator approval program and post-market evaluations to increase the compliant use of PPT and improve its usability and effectiveness. The division has the following goals:

- Develop and implement science-based national guidance for respiratory and other PPT.
- Develop new methods to test effectiveness of PPT for workers, including workers engaged in infection disease activities.
- Create guidance and tools to help employers and workers use PPT as effectively and economically as possible.
- Develop and evaluate innovative PPT designs and test methods to improve comfort, fit, and usability.

NPPTL is also responsible for evaluating and approving respirator models to ensure the expected performance level of respirators used within U.S. workplace settings. The division certifies that



all respirator models used in an occupational setting meet the minimum construction, performance, and respiratory protection standards. The division also conducts site and product audits to ensure respirators continue to meet standards after approval.



NPPTL also participates in international, federal, and consensus PPT standards development activities to facilitate translating research findings and sharing staff expertise.

## Respirator Approval Program

The NIOSH NPPTL Respirator Approval Program is responsible for the testing and approval of respirators used in occupational settings. To be approved, a respirator model must meet the minimum performance requirements defined in Title 42, Part 84 of the Code of Federal Regulations (42 CFR 84). This approval process ensures a minimum level of worker protection from airborne particulates, chemicals, and vapors. The approval process includes a laboratory evaluation of the respirator model, an evaluation of the manufacturer's quality control plan, and audit testing of certified respirators. To facilitate these activities, NPPTL uses Standard Test Procedures. [www.cdc.gov/niosh/npptl/stps/respirator\\_testing.html](http://www.cdc.gov/niosh/npptl/stps/respirator_testing.html)



## NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Chengde Technology Co., Ltd.

Model Tested: KN95 Respirator Protective Mask

Date Tested: May 15, 2020

These findings pertain to the Chengde Technology Co., Ltd., KN95 Respirator Protective Mask. The packaging and labeling for this product indicates that it meets 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).

Thirty respirators were submitted for evaluation. The respirators were sampled into groups of ten 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 99.54% and 95.11%, respectively. All thirty 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 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:** May 15, 2020

**Report Prepared:** May 16, 2020

**Manufacturer:** Chengde Technology Co., Ltd.

**Item Tested:** KN95 Respirator Protective Mask (Sample Group 1 of 3)

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



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	19.1	0.86	0.86	99.14
2	85	21.0	0.88	0.88	99.12
3	85	19.6	0.76	0.76	99.24
4	85	18.8	0.73	0.73	99.27
5	85	18.8	0.79	0.79	99.21
6	85	19.8	0.72	0.72	99.28
7	85	19.8	0.82	0.82	99.18
8	85	19.1	0.80	0.80	99.20
9	85	21.4	0.87	0.87	99.13
10	85	19.3	0.82	0.82	99.18
<b>Minimum Filter Efficiency: 99.12</b>			<b>Maximum Filter Efficiency: 99.28</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.



# NPPTL COVID-19 Response: International Respirator Assessment

**Test:** Modified TEB-APR-STP-0059

**Date Tested:** May 15, 2020

**Report Prepared:** May 16, 2020

**Manufacturer:** Chengde Technology Co., Ltd.

**Item Tested:** KN95 Respirator Protective Mask (Sample Group 2 of 3)

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

Filter	Flow Rate (Lpm)	Initial Filter Resistance (mmH <sub>2</sub> O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency
11	85	18.6	0.86	0.86	99.14
12	85	18.3	4.87	4.87	95.13
13	85	19.9	1.08	1.08	98.92
14	85	19.1	1.90	1.90	98.10
15	85	18.9	1.94	1.94	98.06
16	85	19.2	2.66	2.66	97.34
17	85	18.5	4.89	4.89	95.11
18	85	20.2	1.31	1.31	98.69
19	85	20.4	1.04	1.04	98.96
20	85	22.4	1.10	1.10	98.90
<b>Minimum Filter Efficiency: 95.11</b>			<b>Maximum Filter Efficiency: 99.14</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.
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# NPPTL COVID-19 Response: International Respirator Assessment

**Test:** Modified TEB-APR-STP-0059

**Date Tested:** May 15, 2020

**Report Prepared:** May 16, 2020

**Manufacturer:** Chengde Technology Co., Ltd.

**Item Tested:** KN95 Respirator Protective Mask (Sample Group 3 of 3)

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

Filter	Flow Rate (Lpm)	Initial Filter Resistance (mmH <sub>2</sub> O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency
21	85	23.1	0.61	0.61	99.39
22	85	23.6	0.70	0.70	99.30
23	85	22.2	0.67	0.67	99.33
24	85	22.0	0.50	0.50	99.50
25	85	21.2	0.46	0.46	99.54
26	85	21.8	0.65	0.65	99.35
27	85	21.3	0.77	0.77	99.23
28	85	20.9	0.57	0.57	99.43
29	85	22.8	0.78	0.78	99.22
30	85	22.3	0.50	0.50	99.50
<b>Minimum Filter Efficiency: 99.22</b>			<b>Maximum Filter Efficiency: 99.54</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.
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NPPTL COVID-19 Response: International Respirator Assessment





NPPTL COVID-19 Response: International Respirator Assessment



# NPPTL COVID-19 Response: International Respirator Assessment

