

NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Guangdong Nuokang Medical Technology Co., Ltd.

Model Tested: KN95 Non-Surgical Disposable Particulate FFR

Date Tested: May 27, 2020

These findings pertain to the Guangdong Nuokang Medical Technology Co., Ltd., KN95 Non-Surgical Disposable Particulate FFR. The packaging for this product indicates that it meets GB2626-2006 (the Chinese standard for Respiratory Protective Equipment – Non-Powered Air-Purifying Particle Respirator).

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 97.72% and 95.13%, 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 27, 2020

Report Prepared: May 28, 2020

Manufacturer: Guangdong Nuokang Medical Technology Co., Ltd.

Item Tested: KN95 Non-Surgical Disposable Particulate FFR (Sample Group 1 of 3)

Country of Certification: China (GB2626-2006)

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	14.9	3.26	3.26	96.74
2	85	15.1	2.86	2.86	97.14
3	85	15.2	3.27	3.27	96.73
4	85	17.0	2.28	2.28	97.72
5	85	15.6	3.54	3.54	96.46
6	85	15.9	2.93	2.93	97.07
7	85	16.9	2.85	2.85	97.15
8	85	15.6	3.63	3.63	96.37
9	85	17.2	3.24	3.24	96.76
10	85	16.3	2.85	2.85	97.15
Minimum Filter Efficiency: 96.37			Maximum Filter Efficiency: 97.72		

- 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 27, 2020

Report Prepared: May 28, 2020

Manufacturer: Guangdong Nuokang Medical Technology Co., Ltd.

Item Tested: KN95 Non-Surgical Disposable Particulate FFR (Sample Group 2 of 3)

Country of Certification: China (GB2626-2006)

Filter	Flow Rate (Lpm)	Initial Filter Resistance (mmH ₂ O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency
11	85	17.5	3.33	3.33	96.67
12	85	16.4	3.38	3.38	96.62
13	85	17.8	2.35	2.35	97.65
14	85	16.0	3.00	3.00	97.00
15	85	14.4	4.14	4.14	95.86
16	85	15.8	2.55	2.55	97.45
17	85	16.8	3.78	3.78	96.22
18	85	15.3	2.47	2.47	97.53
19	85	21.1	2.71	2.71	97.29
20	85	16.4	3.55	3.55	96.45
Minimum Filter Efficiency: 95.86			Maximum Filter Efficiency: 97.65		

- 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 27, 2020

Report Prepared: May 28, 2020

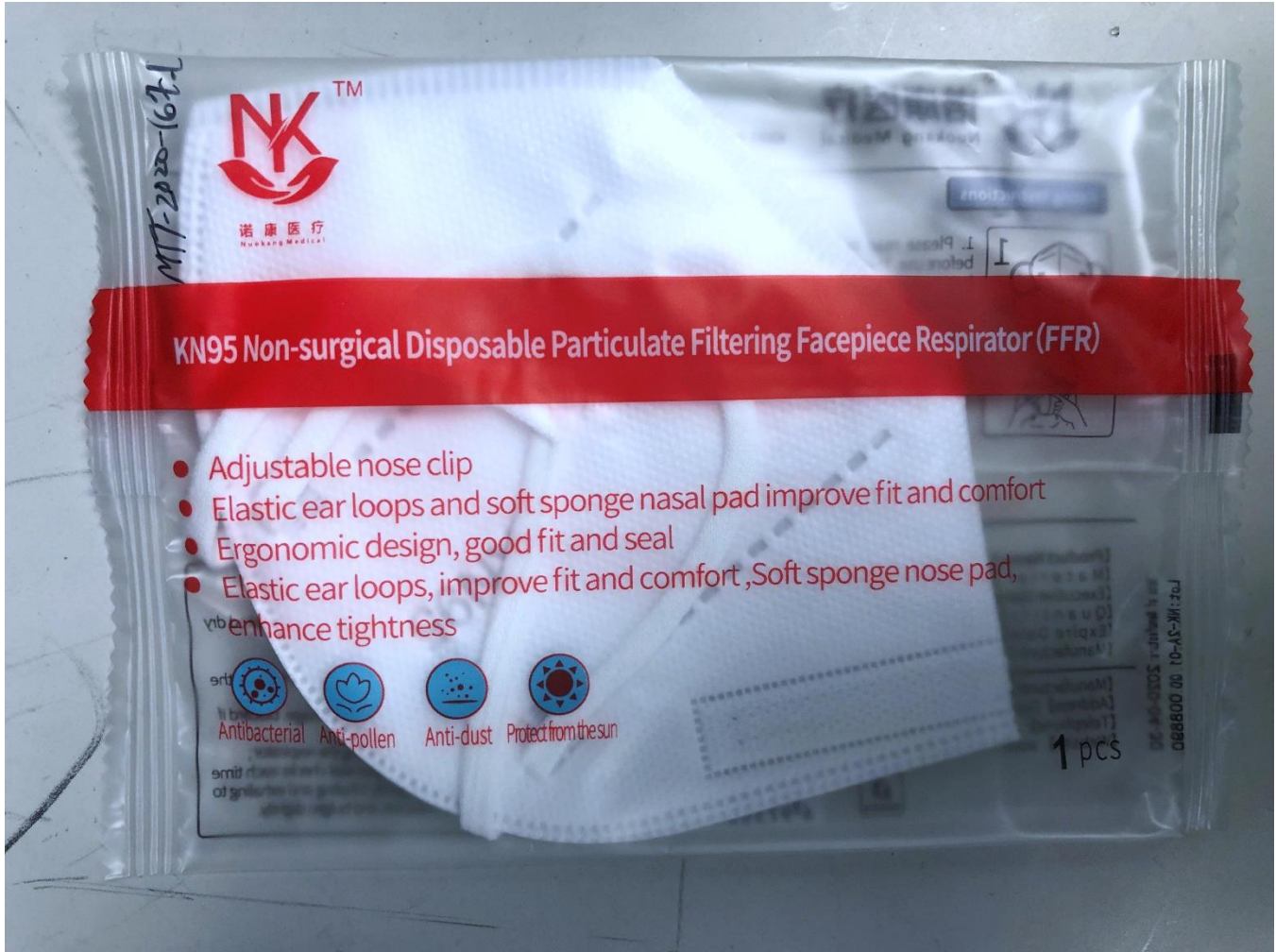
Manufacturer: Guangdong Nuokang Medical Technology Co., Ltd.

Item Tested: KN95 Non-Surgical Disposable Particulate FFR (Sample Group 3 of 3)

Country of Certification: China (GB2626-2006)

Filter	Flow Rate (Lpm)	Initial Filter Resistance (mmH ₂ O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency
21	85	15.1	2.96	2.96	97.04
22	85	17.1	3.10	3.10	96.90
23	85	15.8	3.41	3.41	96.59
24	85	15.7	2.97	2.97	97.03
25	85	16.3	2.86	2.86	97.14
26	85	16.4	3.50	3.50	96.50
27	85	16.0	2.71	2.71	97.29
28	85	16.5	4.44	4.44	95.56
29	85	20.1	3.42	3.42	96.58
30	85	12.2	4.87	4.87	95.13
Minimum Filter Efficiency: 95.13			Maximum Filter Efficiency: 97.29		

- 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.





KN95 Non-surgical Disposable Particulate Filtering Facepiece Respirator (FFR)

Fitting Instructions



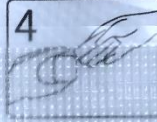
1. Please read the caution statements before use. Take the respirator out of the bag to wear with the nosepiece side up and the ear loops hanging freely.



2. Ensure the nosepiece covers and spans the bridge of your nose and covers the area that the loops around the ears.



3. Make sure that the mouth and nose are completely covered by the respirator. Mold the nose clip to fit snugly around the bridge of your nose. Ensure good seal around the face.



4. Discard the respirator by putting it into a bag for environmental protection.

Date of Manufacture: 2020-04-30
Lot #: NK-2A-01 QG 008890

【Product Name】 KN95 Non-Surgical Disposable Particulate FFR
【Material】 Meltblown non-woven fabric, Ear-loop, Elastic band
【Executive Standard】 GB 2626-2006
【Quantity】 1 pcs
【Expire Date】 Unopened packaging for three years
【Manufacture Date】 see packaging

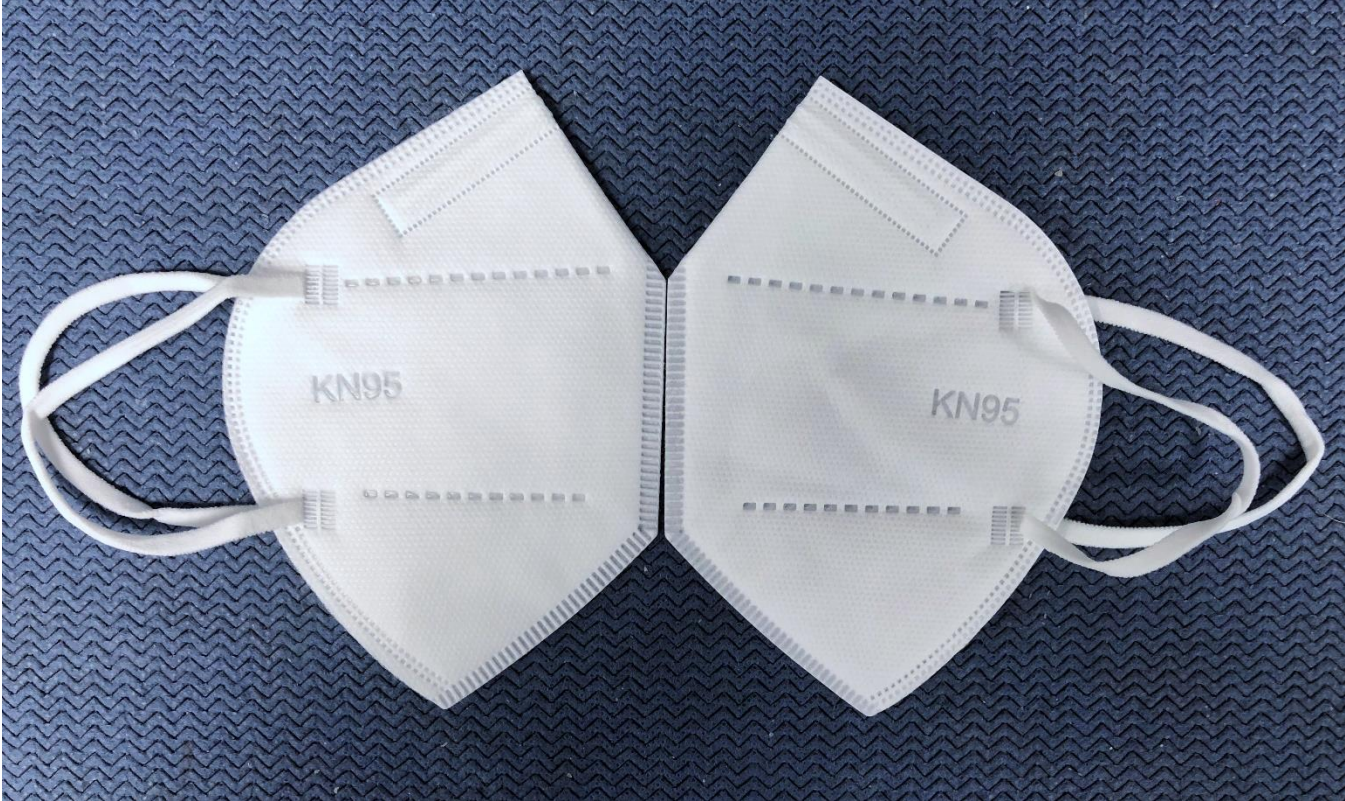
【Manufacturer】 Guangdong Nuokang Medical Technology Co., Ltd.
【Address】 Dongguan City, Guangdong Province, China
【Telephone】 +86-769-81266777
【Website】 www.nuokang.net/respirator



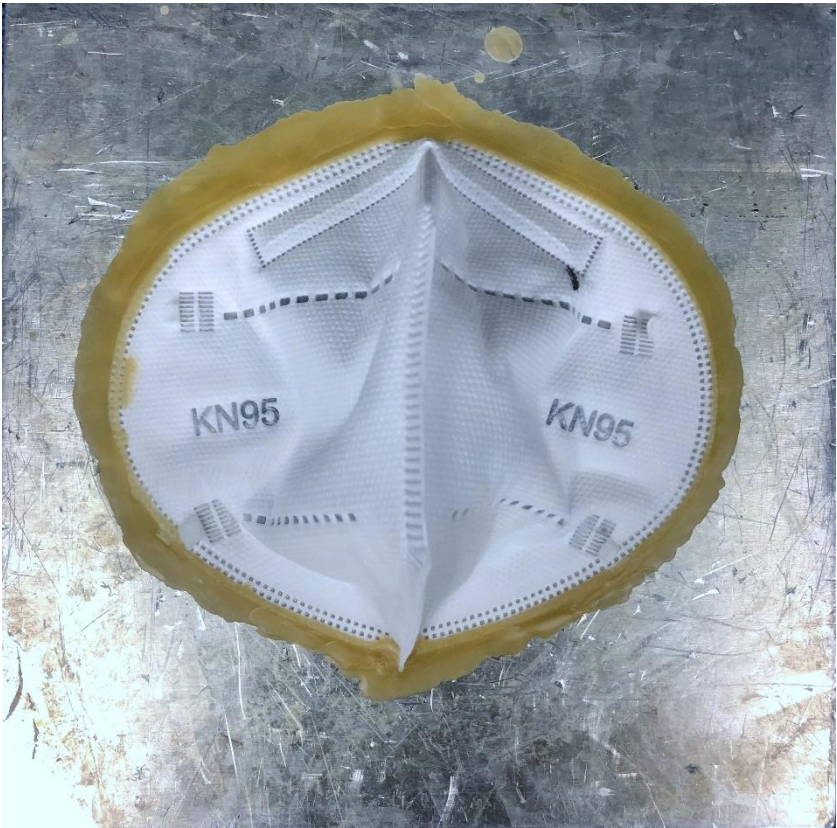
CAUTIONS

1. Please store in a clean, hygienic, and ventilated dry place. Avoid high temperatures;
2. Do not interact with others;
3. Please keep it in a safe place and use it under the supervision and guidance of an adult;
4. Inspect respirator for tears or damage. Discard if discrepancies are found;
5. Wash your hands before wearing the respirator;
6. Perform positive and negative seal checks each time the respirator is used by gently inhaling and exhaling to see if the face piece collapses and bulges slightly.

NPPTL COVID-19 Response: International Respirator Assessment



NPPTL COVID-19 Response: International Respirator Assessment



NPPTL COVID-19 Response: International Respirator Assessment

