

NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Neolithic Tech Co., Ltd.
Model Tested: N95 Medical Protective Mask
Date Tested: April 14, 2021

These findings pertain to the Neolithic Tech Co., Ltd., model N95 Medical Protective Mask. The packaging for this product indicates that it meets AS/NZS 1716:2012 (the Australian standard for Respiratory Protective Devices) 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 samples were tested using the 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 80.63% and 75.41%, respectively. All thirty respirators measured less than 95% filter efficiency.

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 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: April 14, 2021

Report Prepared: April 14, 2021

Manufacturer: Neolithic Tech Co., Ltd.

Item Tested: N95 Medical Protective Mask

Country of Certification: Australia (AS/NZS 1716:2012), European (EN149:2001+A1:2009)

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	5.6	21.79	21.84	78.16
2	85	5.6	20.26	20.26	79.74
3	85	6.1	20.21	20.21	79.79
4	85	6.2	22.19	22.19	77.81
5	85	6.1	20.16	20.16	79.84
6	85	6.0	21.09	21.09	78.91
7	85	5.9	23.23	23.36	76.64
8	85	6.0	20.00	20.00	80.00
9	85	6.0	20.98	20.98	79.02
10	85	6.2	23.05	23.05	76.95
Minimum Filter Efficiency: 76.64%			Maximum Filter Efficiency: 80.00%		

- 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.

Evaluation of International Respirators

Test: Modified TEB-APR-STP-0059

Date Tested: April 14, 2021

Report Prepared: April 14, 2021

Manufacturer: Neolithic Tech Co., Ltd.

Item Tested: N95 Medical Protective Mask

Country of Certification: Australia (AS/NZS 1716:2012), European (EN149:2001+A1:2009)

Filter	Flow Rate (LPM)	Initial Filter Resistance (mmH ₂ O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
11	85	6.2	19.37	19.37	80.63
12	85	6.0	21.05	21.05	78.95
13	85	6.1	23.92	23.92	76.08
14	85	6.3	20.58	20.58	79.42
15	85	6.9	22.51	22.51	77.49
16	85	5.9	24.59	24.59	75.41
17	85	6.0	20.50	20.50	79.50
18	85	6.4	22.05	22.05	77.95
19	85	6.0	23.58	23.58	76.42
20	85	6.1	20.73	20.73	79.27
Minimum Filter Efficiency: 75.41%			Maximum Filter Efficiency: 80.63%		

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Date Tested: April 14, 2021

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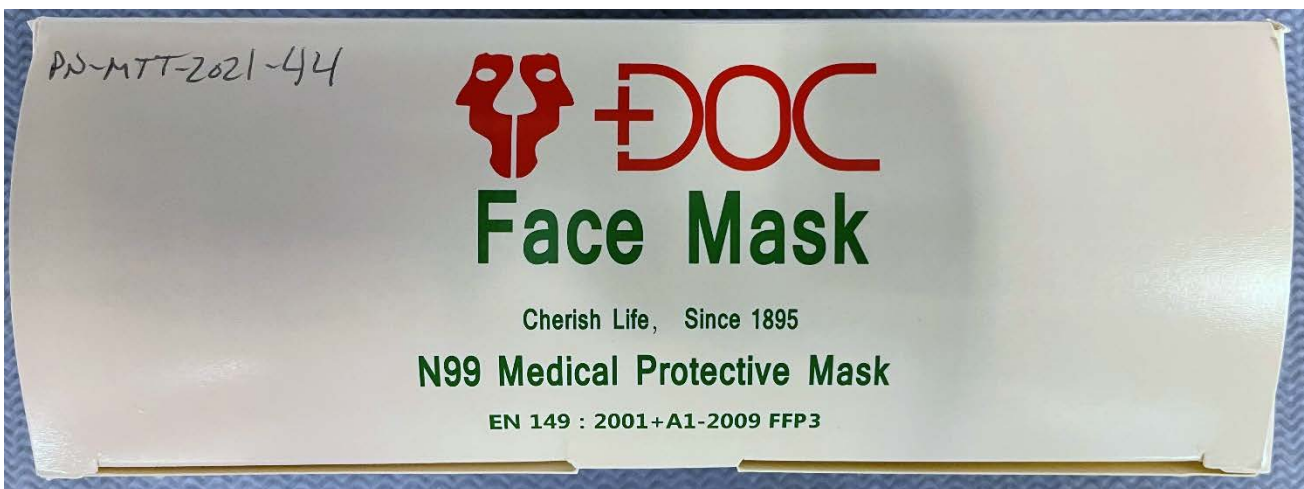
Manufacturer: Neolithic Tech Co., Ltd.

Item Tested: N95 Medical Protective Mask

Country of Certification: Australia (AS/NZS 1716:2012), European (EN149:2001+A1:2009)

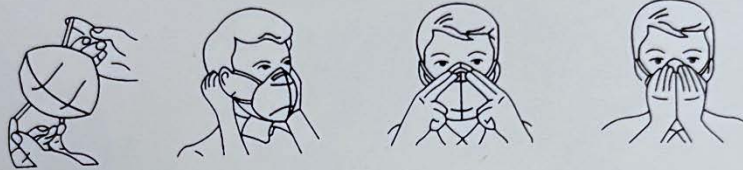
Filter	Flow Rate (LPM)	Initial Filter Resistance (mmH ₂ O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency (%)
21	85	6.7	22.74	22.74	77.26
22	85	6.2	23.44	23.44	76.56
23	85	6.3	20.60	20.60	79.40
24	85	6.6	22.49	22.49	77.51
25	85	6.0	23.23	23.23	76.77
26	85	6.1	20.63	20.63	79.37
27	85	6.2	21.84	21.84	78.16
28	85	6.0	22.50	22.50	77.50
29	85	6.5	20.03	20.03	79.97
30	85	6.3	22.37	22.37	77.63
Minimum Filter Efficiency: 76.56%			Maximum Filter Efficiency: 79.97%		

- 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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- This assessment is not a confirmation that it conforms with any or all of its specifications in accordance with its certification mark.
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INSTRUCTIONS:



1. Open the mask.
2. Hang the ear straps on both ears.
3. Adjust the nose clip.
4. Smooth the mask on both sides.

MATTERS NEEDING ATTENTION:



Do not use if package is damaged.



Do not touch the contaminated surface when removing the mask.



Please put it into the medical garbage can after use.

COUNTRY	CERTIFICATE	Certificate No. held by Neolithic TECH Co.,Ltd	Official Website for Certificate Enquiry
EUR	CE	No. ICR Polska/P6301883	EMAIL: icrpolska@icrqa.com WEB: www.icrpolska.com
USA	FDA	No : HU-M-200328002	https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm
AUS	TGA	ARTG (Certificate No. 332468)	https://tga-search.clients.funnelback.com/s/search.html?query=&collection=tga-artg
CA	MDEL	No : HU-M-200328002	https://health-products.canada.ca/mdel-leim/index-eng.jsp

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PRODUCT INFORMATION :

[Product Name] N95 Medical Protective Mask

[Brand Name] DOC

[Product Grade] Eur: EN14683-2014:TYPE1a; EN 149:2001+A1:2009

Aus: AS/NZS 1716:2012 P3

USA: ASTM F2100-2011 LOW(BFE)

[Mass Detection] Qualified

[Executive Standard] Eur: EN14683-2014; Aus: AS/NZS 1716:2012

USA: ASTM F2100-2011

[Production Date] See the potted line of packing mark.

[Period of Validity] 2020.03-2022.02

[Packaging Specification] 10 pcs/Bag.

[supplier] NEOLITHIC TECH CO.,LTD

[Telephone] +86 20 84557556

[e-mail address] mask@form.net.cn

[Address] No.16, Haishun Road, Nancun Town, Panyu District,
Guangzhou



Made in China

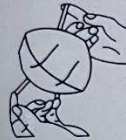


NPPTL COVID-19 Response: International Respirator Assessment

Production date: Mar.2020

Expiration date: Feb.2022

INSTRUCTIONS:



1. Open the mask.



2. Hang the ear straps on both ears.



3. Adjust the nose clip.



4. Smooth the mask on both sides.

MATTERS NEEDING ATTENTION:



Do not use if package is damaged.



Do not touch the contaminated surface when removing the mask.



Please put it into the medical garbage can after use.

PRODUCT INFORMATIONS:

[Product Name] N99 Medical Protective Mask

[Brand Name] DOC

[Product Grade] Eur: EN14683-2014:TYPE1a; Aus: AS/NZS 1716:2012 P3
USA: ASTM F2100-2011 HIGH(BFE)

[Mass Detection] Qualified

[Executive Standard] Eur: EN14683-2014; Aus: AS/NZS 1716:2012
USA: ASTM F2100-2011

[Production Date] See the potted line of packing mark.

[Period of Validity] 2020.03-2022.02

[Packaging Specification] 50 pcs/Bag.

[supplier] NEOLITHIC TECH CO.,LTD

[Telephone] +86 20 84557556

[e-mail address] mask@form.net.cn

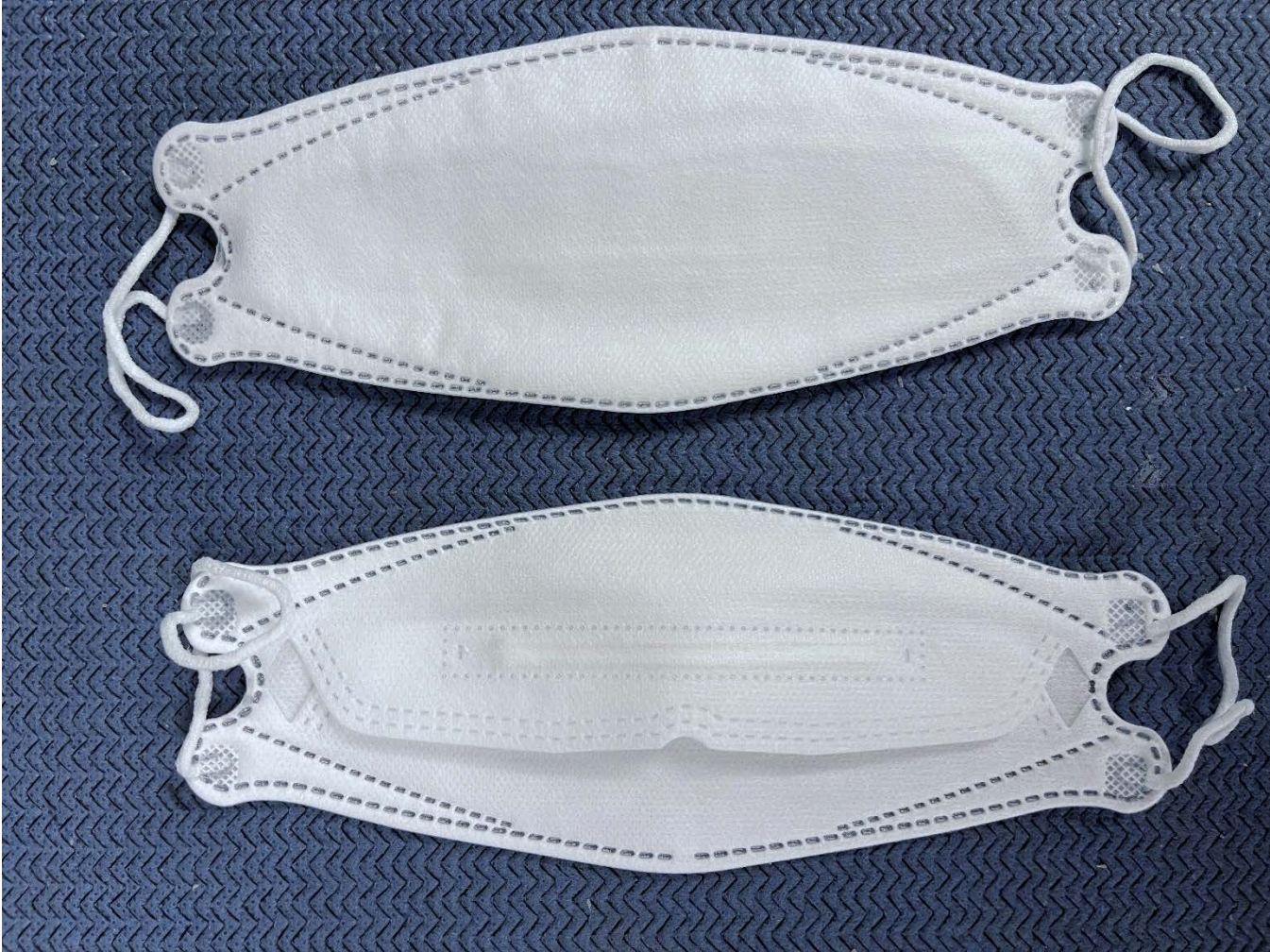
[Address] No.16, Haishun Road, Nancun Town, Panyu District,
Guangzhou



Made in China

COUNTRY	Certificate	Certificate No. held by Neolithic TECH Co.,Ltd	Official Website for Certificate Enquiry
EUR	CE		EMAIL: icrpolska@icrqa.com WEB: www.icrpolska.com
USA	FDA		https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm
AUS	TGA	ARTG (Certificate No. 332468)	https://tga-search.clients.funnelback.com/s/search.html?query=&collection=tga-artg
CA	MDEL		https://health-products.canada.ca/mdel-leim/index-eng.jsp

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