NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Te Yin

Model Tested: TY0929 FFP2 NR Date Tested: April 20, 2020

These findings pertain to the Te Yin, TY0929 FFP2 NR. The labeling on these respirators indicate they meet EN149:2001+A1:2009. This is 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 99.70% and 98.89%, 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 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 <u>Crisis Capacity Strategies (during known shortages)</u>.

Evaluation of International Respirators



Test: Modified TEB-APR-STP-0059

Date Tested: April 20, 2020

Report Prepared: April 20, 2020

Manufacturer: Te Yin

Item Tested: TY0929 FFP2 NR

Country of Certification: Germany (EN149:2001+A1:2009)

Pictures have been added to the end of this report.

Filter	Flow Rate (Lpm)	Initial Filter Resistance (mmH₂O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency
1	85	11.8	0.856	0.883	99.12
2	85	9.4	0.838	1.110	98.89
3	85	12.1	0.238	0.302	99.70
4	85	11.7	0.510	0.510	99.49
5	85	11.4	0.471	0.479	99.52
6	85	12.4	0.716	0.716	99.28
7	85	14.3	0.589	0.589	99.41
8	85	12.1	0.504	0.516	99.48
9	85	11.9	0.777	0.784	99.22
10	85	12.9	0.435	0.521	99.48
Minimum Filter Efficiency: 98.89			Maximum Filter Efficiency: 99.70		

- 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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