

AUTHORIZED AGENT: Claudine DeNiro CNGA WORLDWIDE LLC www.CNGA.us

E mail: CD@CNGA.us

Office: +1 (646)-515-3600 Mobile: +1(310)299-3007 WhatsApp: https://wa.

me/13102993007 D-U-N-S #

036807739

SAMS # 8QXJ4



## STOP C-19 NIOSH N95

CONTACT YOUR LOCAL REP

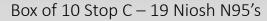
2021

### STOP C-19 NIOSH N95











#### N95 FDA 510K



#### DEPARTMENT OF HEALTH & HUMAN SERVICES

NIOSH Reference: TN-22527 Mfr. Reference: AOK41 Centers for Disease Control
and Prevention (CDC)
National Institute for Occupational
Safety and Health (NIOSH)
National Personal Protective
Technology Laboratory (NPPTL)
626 Cochrans Mill Road
Pittsburgh, PA 15236-0070
Phone: 412-386-4001
Fax: 412-386-4051

January 25, 2019

Mr. Francis Nathan AOK Tooling Limited 13963 Ramona Avenue, Suite D Chino, California 90710

Dear Mr. Nathan:

The National Institute for Occupational Safety and Health (NIOSH) has reviewed your request accepted September 17, 2018. This request was for approval of the model 20180022V 3D N95 B Mask+ air-purifying filtering-facepiece respirator with exhalation valve (part numbers 20180022V-XI, 20180022V-L, and 20180022V-M) for protections against particulates at N95 filter efficiency level. The complete respirator configurations are detailed on the assembly matrix, file name 20180022V\_Assembly\_Matrix\_AMa0.xlsx, revision A/0, dated August 28, 2018.

Testing was not assigned as the models are identical in material and surface area as those tested successfully under TN-22036.

This request is granted. Approvals are granted only for documentation written in the English language. It is the manufacturer's responsibility to correctly translate materials desired to be produced in languages other than English. Approval number TC-84A-8128 has been assigned. This respirator is approved for protection against particulates at N95 filter efficiency level.

The final respirator labels are included as attachments to this letter. The abbreviated labels have been accepted as submitted. The cautions and limitations which apply to these approvals are on the approval labels. Only those assemblies affected by this request, or where new approval numbers are assigned, apply to this approval action. Production approval labels cannot include information on unapproved configurations.

The approved assemblies consist of the parts as listed on the approval labels and the assembly matrix. Parts are to be marked with the numbers indicated on the approval label in a legible and permanent manner (marking cannot be removed without evidence of its previous presence).

This certificate of approval is not an endorsement of the respirators by NIOSH, and such endorsement shall not be stated or implied in advertisements or other publicity. However, you may publicize the fact that these respirators have met the requirements of Title 42, Code of Federal Regulations, Part 84 (42 CFR 84).

Page 2- Mr. Francis Nathan- TN-22527

No changes may be made to any respirators and accompanying documentation without prior written approval of NIOSH. Requests for changes must be submitted to NIOSH and a modification of this approval must be granted before changes are made.

Sincerely

Collien Millin

Jeffrey Peterson
Chief, Conformity Verification and
Standards Development Branch

Enclosures





#### Sanitation & Environment Technology Institute, Soochow University, Final Report

Report Number: SDWH-M201702136-1

Skin Sensitization Test of
3D N95 Mask With Valve、N95 Plain Mask
using ISO 10993-10:2010 Test Methods
Closed-patch test
0.9% Sodium Chloride Injection Extract

Sponsor AOK Tooling Limited

Manufacturer

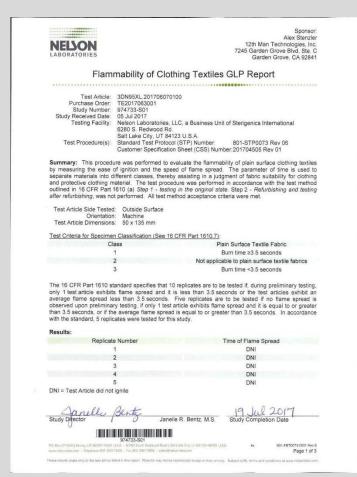
**AOK Tooling Limited** 

Sanitation & Environment Technology Institute, Soochow University
Tel: 0512-65880038 Fax: 0512-65880034 Email: sudaweihuan@suda.edu.cn PC: 215123
Add: No.199 Ren'ai Road, Suzhou Industrial Park, China http://yxbfzb.suda.edu.cn
Page 1 of 12

FDA 510K FDA 510K



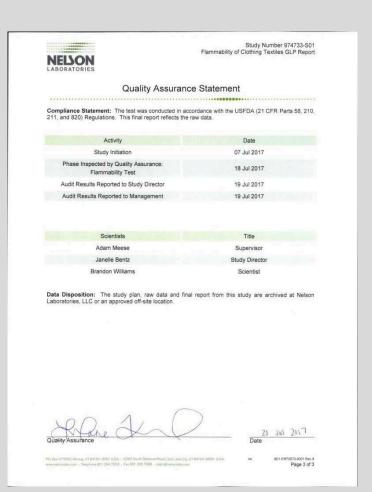
#### N95 FLAMMABILITY TESTING



Nelson Testing Data Flammability

Study Number 974733-S01 Flammability of Clothing Textiles GLP Report **NELYON** Test Method Acceptance Criteria: Flame length must be approximately 16 mm (~% in) from the flame tip to the opening in the gas nozzle. **Procedure:** Test articles were prepared by cutting the material into approximately 50 x 150 mm swatches. Preliminary testing to establish the orientation and side of the test article to test was performed. The side and orientation that burned the fastest was used to test the test articles. Each test article was clamped into the specimen holder and placed in an oven maintained at 105 ± 3°C for 30 ± 2 minutes. The test articles were then placed in a desiccator for a minimum of 15 minutes prior to The flame length of the flammability tester was adjusted to approximately 16 mm prior to testing. Test articles were placed on the flammability rack and the stop cord was strung through the guides. The flammability timer was zeroed and testing was started. When the flame reached the stop cord, the timer stopped, and the results were recorded. Testing was terminated for test articles that did not exhibit flame spread beyond the initial application of the flame.

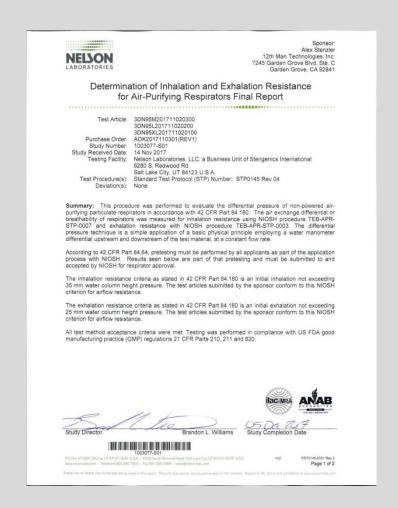
Nelson Testing Data Flammability Continue

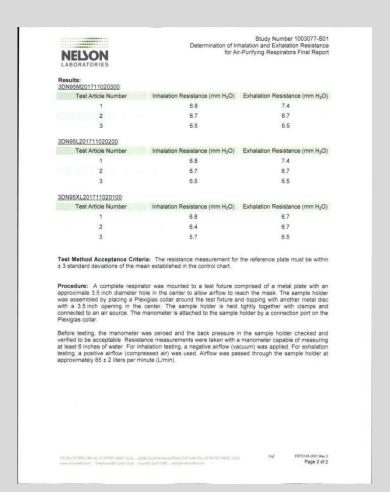


Nelson Lab QA



#### N95 AIR FILTRATION TESTING





Nelson Testing Data Air Purifying

Nelson Testing Data Air Purifying



#### N95 PACKAGING





Pallet





**Entire Box** 



Top View



Carton



Angle Box

Side View



## N95 PRODUCTION FACILITY













# STOP C-19 NIOSH N95

CONTACT YOUR LOCAL REP

2021