

NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Dongguan Oukangda Medical Technology Co., Ltd.

Model Tested: Kangerda KN95 Particulate Respirator

Date Tested: April 29, 2020

These findings pertain to the Dongguan Oukangda Medical Technology Co., Ltd., Kangerda KN95 Particulate Respirator. The packaging 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).

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 93.68% and 90.28%, respectively. All ten respirators measured less 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: April 29, 2020

Report Prepared: May 4, 2020

Manufacturer: Dongguan Oukangda Medical Technology Co., Ltd.

Item Tested: Kangerda KN95 Particulate Respirator

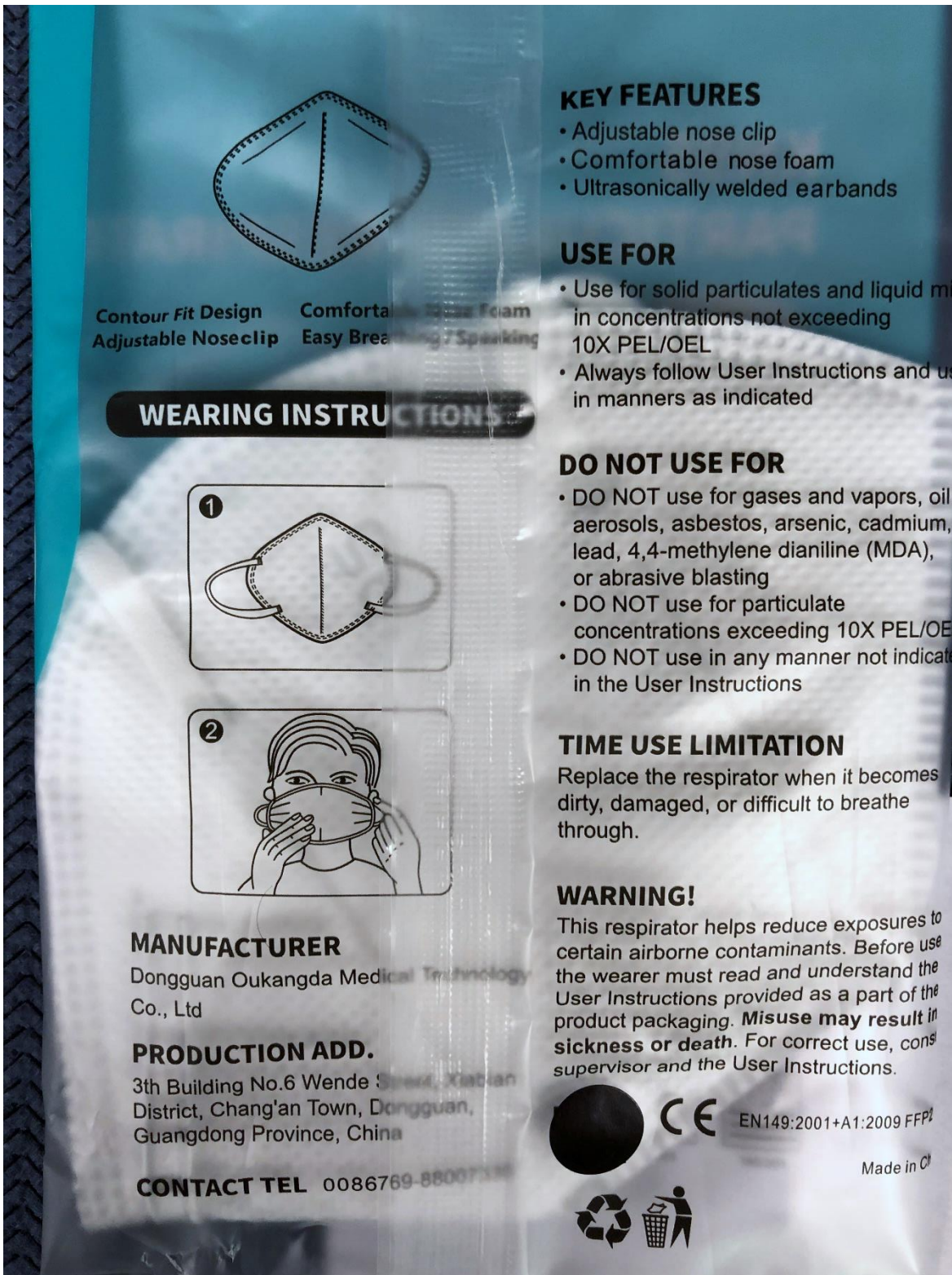
Country of Certification: China (GB2626-2006, EN149:2001+A1:2009)

Pictures have been added to the end of this report.

Filter	Flow Rate (Lpm)	Initial Filter Resistance (mmH ₂ O)	Initial Percent Leakage (%)	Maximum Percent Leakage (%)	Filter Efficiency
1	85	12.8	7.52	7.52	92.48
2	85	6.2	8.53	8.53	91.47
3	85	6.3	8.71	8.71	91.29
4	85	6.8	6.32	6.32	93.68
5	85	6.7	9.72	9.72	90.28
6	85	6.0	8.07	8.07	91.93
7	85	6.6	8.10	8.10	91.90
8	85	6.1	8.75	8.75	91.25
9	85	6.0	9.16	9.16	90.84
10	85	6.0	9.26	9.26	90.74
Minimum Filter Efficiency: 90.28			Maximum Filter Efficiency: 93.68		

- 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.





The image shows the packaging for a white respirator. The top left features a technical drawing of the respirator with a dashed line indicating the nose clip area. Below this, the text 'Contour Fit Design' and 'Adjustable Noseclip' is on the left, and 'Comfortable Nose Foam' and 'Easy Breathing / Speaking' is on the right. A black banner with white text reads 'WEARING INSTRUCTIONS'. Below this are two numbered diagrams: 1 shows the respirator from the front, and 2 shows a person wearing it. The right side of the packaging contains sections for 'KEY FEATURES', 'USE FOR', 'DO NOT USE FOR', 'TIME USE LIMITATION', and 'WARNING!'. At the bottom, there is manufacturer information, production address, contact details, and certification marks including CE and EN149:2001+A1:2009 FFP2, along with a 'Made in China' label and recycling symbols.

KEY FEATURES

- Adjustable nose clip
- Comfortable nose foam
- Ultrasonically welded earbands

USE FOR

- Use for solid particulates and liquid mist in concentrations not exceeding 10X PEL/OEL
- Always follow User Instructions and use in manners as indicated

DO NOT USE FOR

- DO NOT use for gases and vapors, oil aerosols, asbestos, arsenic, cadmium, lead, 4,4-methylene dianiline (MDA), or abrasive blasting
- DO NOT use for particulate concentrations exceeding 10X PEL/OEL
- DO NOT use in any manner not indicated in the User Instructions

TIME USE LIMITATION

Replace the respirator when it becomes dirty, damaged, or difficult to breathe through.

WARNING!


This respirator helps reduce exposures to certain airborne contaminants. Before use the wearer must read and understand the User Instructions provided as a part of the product packaging. **Misuse may result in sickness or death.** For correct use, consult supervisor and the User Instructions.

MANUFACTURER
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CE EN149:2001+A1:2009 FFP2
Made in China



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