

NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Baoji Taidakang Medical Technology Co., Ltd

Model Tested: Butterfly Ear Hanging

Date Tested: May 13, 2020

These findings pertain to the Baoji Taidakang Medical Technology Co., Ltd., model Butterfly Ear Hanging. The labeling for these respirators indicate they meet GB19083-2010 (the Chinese standard for Technical Requirements for Protective Face Mask for Medical Use).

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 99.56% and 99.09%, 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.

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 13, 2020

Report Prepared: May 13, 2020

Manufacturer: Baoji Taidakang Medical Technology Co., Ltd

Item Tested: Butterfly Ear Hanging

Country of Certification: China (GB19083-2010)

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	13.3	0.67	0.67	99.33
2	85	12.3	0.91	0.91	99.09
3	85	12.5	0.76	0.76	99.24
4	85	11.1	0.90	0.90	99.10
5	85	14.0	0.44	0.44	99.56
6	85	13.1	0.97	0.97	99.03
7	85	12.2	0.64	0.64	99.36
8	85	14.7	0.49	0.49	99.51
9	85	13.4	0.85	0.85	99.15
10	85	13.5	0.46	0.46	99.54
Minimum Filter Efficiency: 99.09			Maximum Filter Efficiency: 99.56		

- 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.

MTT-2020-47.3 95-1



STERILE STERILE EO

Medical Protective Mask N95

[Model] Butterfly ear hanging 15.5cmx10cm

[Intended use] It is used in medical working environment to filter particles in the air, block droplets, blood, body fluids, secretions, etc. The product consists of mask body, nose clip and mask belt.

[Composition] SMSS Material Outer layer is Spunbond, Second layer is Meltblown Thind layer is hot air cotton, Inner layer is Spunbond.

[Usage]

- 1) Open the mask flat, face the face of the mask without nose clip, so that the nose clip is located above the mask;
- 2) Hold one side of the ear band with both hands and put the mask against the chin;
- 3) Pull the ear band behind the ear and adjust the ear band until it feels as comfortable as possible;
- 4) Place the fingers of both hands in the middle of the metal nose clip and press inward while moving the fingertips along the nose clip to the sides until the clip is fully pressed into the shape of the bridge of the nose. Using only one hand to pinch the nose clip may affect the tightness of the mask;
- 5) Before entering the work area, the mask must be checked for tightness with the face.

[Precaution/warning]

- 1) Respiratory protective equipment not applicable to protection against harmful gases and vapors. Not suitable for anoxic environment, underwater operations, escape and fire respiratory protective equipment.
- 2) Before use, please check whether the packaging is in good condition, confirm the external packaging mark, production date and validity period, and use within the sterilization period.
- 3) This product is a disposable product and is not allowed to be reused.
- 4) The product has been sterilized with ethylene oxide.
- 5) If the mask is damaged, dirty, or breathing resistance becomes large, please leave the contaminated area and replace the respirator.

[Service life] 2 years

[Execute the standard code] GB 19083-2010

[Production License No.] Shaanxi pharmaceutical supervision machinery production license No. 20200014

[Registration Certificate No. & Product Technical Requirements No.] Shaanxi Machinery Injection No. 20202140026

[Manufacture Date/Batch Number] See package

[Storage and transportation conditions] Should be stored in no corrosive gases, cool, dry, well-ventilated environment, and away from fire and inflammables; Transport by airtight or van.

[Manufacture] Baoji Taidakang Medical Technology Co., Ltd

[Tel] 0917-6786999 / 6782999 [Website] www.tdky.com

1 pcs/ bag

BFE ≥ 99% EN14683 FDA



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Made in China

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