

NPPTL COVID-19 Response: International Respirator Assessment

Manufacturer: Oco Healthcare Co., Ltd.

Model Tested: Clapiel Health Yellow Dust Prevention Mask 36° (KF94)

Date Tested: November 9, 2020

These findings pertain to the Oco Healthcare Co., Ltd., Clapiel Health Yellow Dust Prevention Mask 36° (KF94). The KF94 on the packaging for this product implies that these respirators were made in Korea. However, there is no indication that the product meets the requirements of KMOEL-2017-64 (the Korean standard).

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 98.91% and 98.02%, 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 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: November 9, 2020

Report Prepared: November 10, 2020

Manufacturer: Oco Healthcare Co., Ltd.

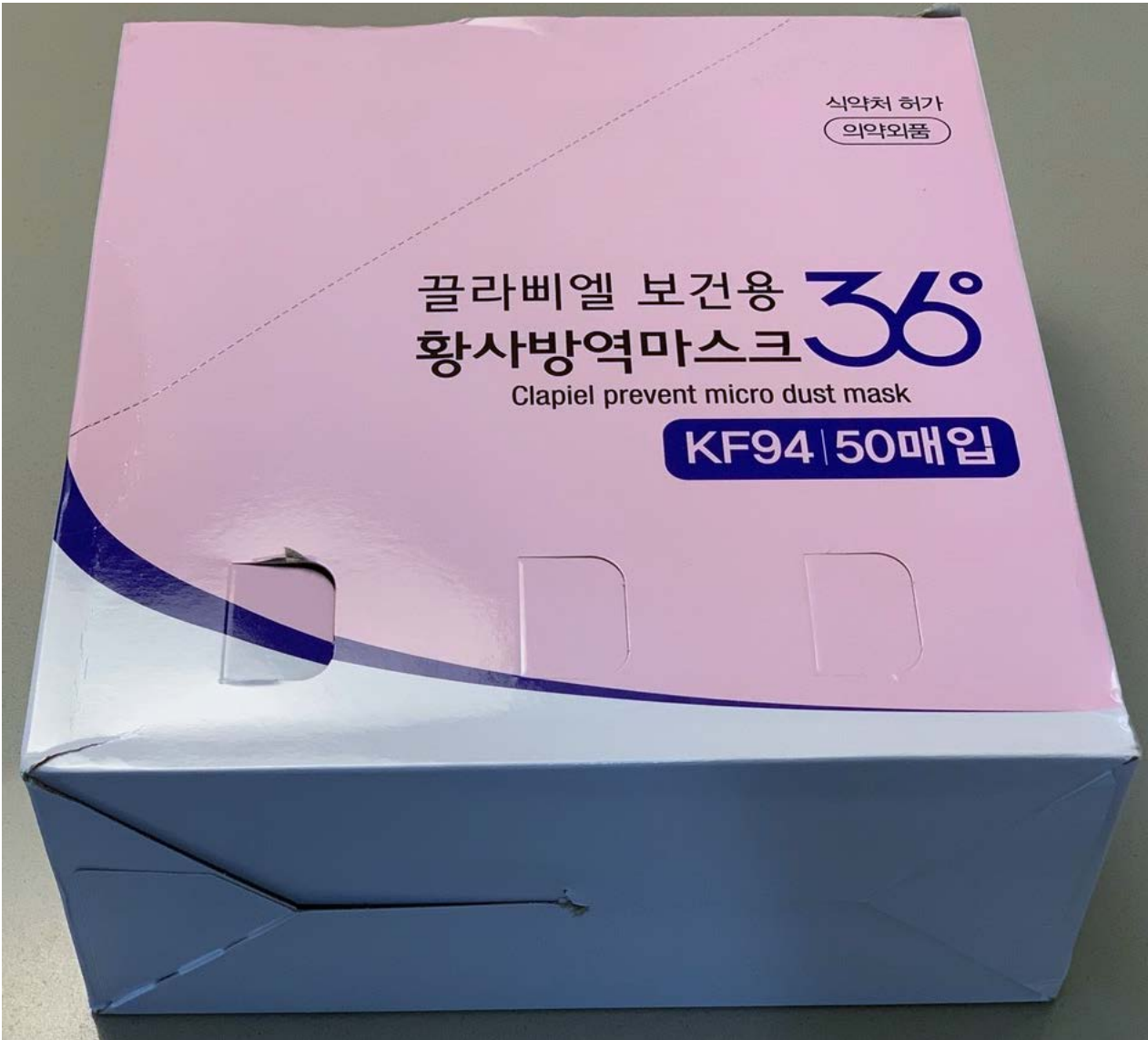
Item Tested: Clapiel Health Yellow Dust Prevention Mask 36° (KF94)

Country of Certification: UNKNOWN

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	10.0	1.61	1.61	98.39
2	85	10.0	1.09	1.09	98.91
3	85	8.9	1.49	1.49	98.51
4	85	10.5	1.44	1.44	98.56
5	85	10.0	1.33	1.33	98.67
6	85	9.1	1.72	1.72	98.28
7	85	10.3	1.46	1.46	98.54
8	85	10.4	1.72	1.72	98.28
9	85	9.6	1.98	1.98	98.02
10	85	10.0	1.61	1.61	98.39
Minimum Filter Efficiency: 98.02			Maximum Filter Efficiency: 98.91		

- 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.



골라비엘 보건용
황사방역마스크 36°
Capit prevent micro dust mask

착용방법

1. 마스크를 코와 턱을 감싸도록 안면에 맞춘다.
 2. 안쪽 고정끈을 귀에 걸어 위치를 고정시킨다.
 3. 양 손의 손가락으로 코 밀착부분이 코에 밀착되도록 플립을 눌러준다.
 4. 양 손으로 마스크 전체를 감싸고 공기 누설을 체크하면서 안면에 밀착되도록 조정한다.
- * 위와 같은 방법으로 착용해야 마스크 착용효과를 최대화 할 수 있다.

사용상 주의사항

1. 수건, 휴지 등을 사용하여 호흡기를 감싸 다음 그 위에 착용하지 마십시오.
2. 산소농도 18% 미만인 밀폐된 장소에서 사용하지 마십시오.
3. 면제를 피그리프러거나 변형하여 사용하지 마십시오.
4. 마스크 안쪽이 오염되었을 시는 사용하지 마십시오.
5. 세탁하여 사용하지 마십시오.
6. 임산부, 호흡기·심혈관 질환자, 어린이, 노약자 등 마스크 착용으로 불편한 경우 사용을 중지하고, 필요 시 의사 등의 전문가와 상의하시기 바랍니다.

「약사법」에 따른 의약외품 표시사항

- 제품명 : 골라비엘 보건용 황사방역마스크(상심육도(KF94)(흰색)(대형)) • 매수 : 50매
 - 마스크의 종류 : 보건용 마스크(KF94) • 의약외품
 - 판매원 : (주)오스코리아 경기도 성남시 분당구 판교역로 240, 428호
 - 제조원 : (주)오코헬스케어 강원도 원주시 문막읍 문막공단길 250
 - 기술제휴 : (주)한국유니온제약
 - 소비자센터 : 1544-3447
 - 저장방법 : 밀폐용기, 실온보관 (1~30°C)
 - 재조번호 및 사용기한 : 별도표기
 - 효능효과 : 황사, 미세먼지 등 입자성 유해물질 및 감염원으로부터 호흡기 보호
 - 원료의 명칭 : 겔라(부직포), 필터(부직포), 안감(부직포) 중간재(부직포), 끈(고정용 - 폴리우레탄나일론끈) 코핀(폴리프로필렌피복철사)
- * 본 제품은 공정거래위원회 고시 소비자분쟁해결 기준에 의거 교환 또는 보상받을 수 있습니다.



SAMSUNG
100 Million KRW
Product Liability

HOW TO USE

1. Unfold the mask, 2. Cover the folded middle of the mask to the nose,
3. Place both straps on the ear to secure their position,
4. Adjust the nose bridge to perfectly fit the face.

CAUTIONS

1. Do not cover the nose with a towel or tissue and wear the mask on top of it,
2. Do not use in closed area with an oxygen content of less than 18%
3. Do not crush or deform the mask, 4. Do not use the mask if it is contaminated inside,
5. Do not wash the mask,
6. In case the mask is uncomfortable to wear, such as pregnant women, respiratory patients, cardiovascular patients, children, and the elderly, please stop using and consult a doctor or specialist if necessary.

MATERIALS

Surface(Non-woven Fabric), Filter(Non-woven Fabric), Lining(Non-woven Fabric), Supporting Body(Non-Woven Fabric), Nose Bridge(Polyethylene Sheath Wire), Strap(Polyurethane nylon strap)

HOW TO STORAGE

Store at room temperature in sealed container (1°C~30°C)

MADE IN KOREA







Clapiel

식약처 허가
의약품

클라삐엘 보건용 36°
항사방역마스크
Clapiel prevent micro dust mask

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「약사법」에 따른 의약품 표시사항

- 제품명 : 클라삐엘 보건용 항사방역마스크36° (KF94) • 매수 : 1매
- 제조원 상호 및 주소 : (주)오코엘스케어
강원도 원주시 문막읍 문막공단길 250
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중간재(부직포), 끈(고정용 - 폴리아우레탄나일론끈)
코연(폴리프로필렌 피복철사)

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EXP2023.07.02

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NPPTL COVID-19 Response: International Respirator Assessment



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