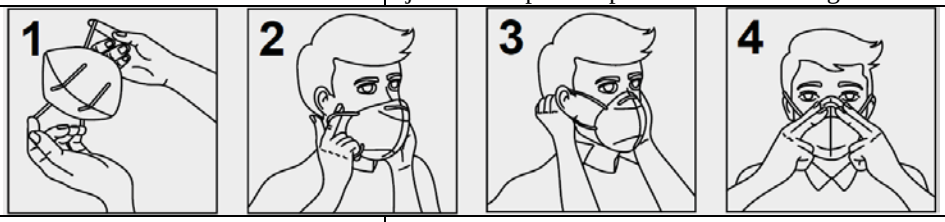
DOSSIER TÉCNICO
MASCARILLA ANTI-PARTICULA FFP2 NR
JOCCA PHARMA YD-002
V.1.0 JUNIO 2020

FICHA TÉCNICA
"MASCARILLA ANTI-PARTÍCULAS FFP2"
Rev.01 - Mayo 2020

Marca	JOCCAPHARMA
Ref.	YD-002
Modelo	6852
Descripción	Mascarilla antipartículas
Clasificación	EPI. Tipo: FFP2 NR bajo la norma EN149:2001+A1:2009 (equivalente UNE-EN149:2001+A1:2010)
EPI Categoria	III
Rendimiento	≥92%
Indice de Fuga	11%
Embalaje	6582 1 pcs / bolsa de plástico 464 unidades / caja master
Tamaño	Aprox. Caja master 58 x 32 x 29 cm Peso bruto 4.9 kgr Peso Neto 4.2 kgr
Rango de temperatura de almacenamiento	-30ºC - +40ºC
Humedad de almacenamiento	<80%
Caducidad	2 años
Dimensiones	Largo 140 ± 5 mm Anchura 125 ± 5 mmb Ancho (desenrollado) 190 ± 5 mm Tira elástica 160 ± 5 mm Pieza rígida nariz 90 (± 2 mm) x 5 (± 0.2 mm) x 0.5(± 0.1 mm) mm
Composición	5 Capas
Material	Capa 1 Polipropileno, blanco, superficie suave Textil no tejido 50 gr/m^2 Capa 2 Polipropileno, blanco, textil no tejido (soplado de fusión) 25 gr/m^2 Capa 3 Polipropileno, blanco, textil no tejido (soplado de fusión) 30 gr/m^2 Capa 4 Polipropileno, blanco, textil no tejido 25 gr/m^2 Capa 5 Polipropileno, blanco, textil no tejido 25 gr/m^2 Pieza rigida nariz aluminio
Reutilización	Producto de un solo uso
Partes	Filtro + correa de ajuste
Tamaño de filtrado	Partículas de 0,2 a 2 micras de diámetro
Modo de empleo	INSTRUCCIONES de USO: 1.- Sostenga la mascarilla en la mano con la boquilla en la punta de los dedos permitiendo que las cintas para la cabeza cuelguen libremente debajo de su mano 2.- Presione la mascarilla firmemente contra su cara con la boquilla en el puente de la nariz. 3.- Estire la cintas sobre la cabeza y colóquelas detrás de las orejas. 4.- Moldee la pieza metálica a la forma de su nariz. 5.- Para probar el ajuste, coloque ambas manos sobre el respirador y exhale vigorosamente. Si el aire fluye alrededor de

	su nariz. Apriete la pieza nasal, si el aire gotea alrededor de los bordes, vuelva a colocar las correas para un mejor ajuste. 6 Recuerde, el cumplimiento cuidadoso de estas instrucciones de ajuste es un paso importante en el uso seguro de la mascarilla.
	
ADVERTENCIA	Lea y comprenda antes de usar las siguientes indicaciones 1.- Una mascarilla debidamente seleccionada es esencial para proteger su salud. Antes de usar este o cualquier otro producto, consulte a un Higienista industiral o profesional de Seguridad Ocupacional para determinar su idoneidad para el uso previsto. Este producto no protegerá contra vapores, gases o vapores, no lo use en operaciones de pintura en aerosol. 2.- No utilizar en operaciones de arenado. 3.- Este producto no suministra oxígeno. Use esta mascarilla solo en áreas bien ventiladas que contengan suficiente oxígeno (18% de oxígeno) para no poner en riesgo su vida 4.- No lo use cuando las concentraciones de contaminantes son desconocidas o inmediatamente peligrosas para la vida. 5.- Abandone el área de trabajo de inmediato si: a) la respiración se vuelve difícil, o b) se producen mareos u otros signos de angustia. 6.-Si el usuario tiene alguna enfermedad o trastorno, consulte a un médico con licencia para determinar la idoneidad de uso. 7.- El vello facial y ciertas características faciales pueden impedir el uso efectivo de este producto. 8.- Utilice la mascarrilla sólo de acuerdo con las instrucciones, etiquetas y limitaciones relacionadas con este producto. 9.- No altere ni modifique este producto de ninguna manera. 10.- Siga las instrucciones del fabricante para ajustar la mascarilla a la cara. 11.- Mantenga las mascarillas en su embalaje lejos de la luz solar directa hasta su uso. 12.- Estas máscaras de filtración no deben usarse en alambiques, tanques, espacios cerrados ni en ninguna circunstancia en la que pueda haber presencia de gas, o en atmósferas deficientes en oxígeno. 13.-Para uso sólo contra aerosoles sólidos. 14.- Esta es una mascarilla de un solo uso. Deseche la mascarilla usada después de un solo uso (no más de 8 horas)
Limitaciones:	1.- POLVO con un NEP (Nivel de exposición permisible) no inferior a 0.05 miligramos por metro cúbico de aire o 2 millones de partículas por pie cúbico de aire. Estos incluyen, entre otros, polvo de carbón, algodón, cadmio, cromo, plomo, manganeso, aluminio, harina, mineral de hierro y sílice libre que resulta principalmente de la desintegración de un sólido tal como ocurriría en la minería, extracción, trituración, molienda o procesamiento general de minerales y otros materiales. 2.- Para uso sólo contra aerosoles sólidos y a base de agua. Los aerosoles a base de agua son aquellos producidos a partir de soluciones y / o suspensiones de materiales en partículas en el agua de modo que el único contaminante en el lugar de trabajo se atribuya a este material sólido. 3.- Esta mascarilla no es adecuada para desinfectar o limpiar
Almacenamiento y vida útil:	Las mascarillas deben colocarse en un recipiente y almacenarse en una atmósfera limpia, fresca y seca para garantizar que estén

	protegidos del polvo, productos químicos, humedad, calor excesivo y luz solar directa. El incumplimiento de estos requisitos puede afectar el rendimiento y la vida útil del producto.
Limpieza y Mantenimiento:	No se require
Directivas y Normas Aplicables	Reglamento **UE 2016/425** de 9 de marzo de 2016 relativo a equipos de protección individual (EPI). Norma **EN 149:2001+A1:2009** (equivalente UNE-EN149:2001+A1:2010) de dispositivos de protección respiratoria, medias máscaras filtrantes de protección contra partículas.
Laboratorio Notificado	Universal Certification LTD STI Notified Body 2163 Necip Fazıl Bulvarı Keyap Sitesi E2 Blok No:44/84 Yukarı Dudullu Ümraniye / İSTANBUL / TÜRKİYE
Fabricante	Guangdong Yidao Medical Technology Co., Ltd Room 302, Building 2, No.1, Lane 1, Xiju Road, Hengli, Dongguan City, Guangdong Province, P.R. China
Importado por:	QUALIMAX INTERNATIONAL, S.L. Calle Tarraca 12. Pol. Ind. Plaza. 50197 Zaragoza

EU DECLARATION OF CONFORMITY

1. **Brand name:** VITAL VIDA PHARMA
   Article : DISPOSABLE FILTERING HALF MASK
   Total Inwards Leakage: Class FFP2
   Category: PPE Category III
   Ref.: YD-002
   Mod.: 6852

2. **Name and address of the manufacturer:**
   GUANGDONG YIDAO MEDICAL TECHNOLOGY Co., LTD
   Room 302, Building 2, No.1, Lane 1, Xiju Road, Hengli, Dongguan City, Guangdong Province, China

3. **This declaration of conformity is issued under the sole responsibility of the manufacturer.**

4. **Object of the declaration:**
   Brand: VITAL VIDA PHARMA
   Ref.: YD-002
   Mod.: 6852

5. **The object of declaration described above is in conformity with the** relevant Union regulation EU 2016/425

6. **References to the relevant harmonized standards used:**
   CE : EN149:2001 + A1:2009
   FFP2 NR

All the CE technical documents, which are true, have been verified by the manufacturer and the notified body.

Notified Body: UNIVERSLA CERTIFICATION Co. Ltd.Notified Body **2163**
Necip Fazıl Bulvarı Keyap Sitesi E2 Blok No:44/84
Yukarı Dudullu Ümraniye / İSTANBUL / TÜRKİYE

Certification number: 2163-PPE-639 (EU Type Examination Certificate)
Issue date: 28/04/2020
Validity period: 27/04/2025

2163-PPE-639/01 (Module C2)
Issue date: 28/04/2020
Validity period: 27/04/2021

Date, Signed and stamped

UNIVERSAL

UNIVERSAL
CERTIFICATION

NB 2163

CERTIFICATE OF CONFORMANCE

Certificate Nr: 2163-PPE-639/01

Respiratory protective devices, filtering half masks to protect against particles manufactured by

Guangdong YIDAO Medical Technology Co., LTD.

at the following manufacturing site

Room 302, Building 2, No. 1, Lane 1, Xiju Road, Hengli, Dongguan City, Guangdong Province, P. R. CHINA

Continues to fulfil the requirements of

EN 149:2001 + A1:2009 Respiratory Protective Devices - Filtering Half Masks to Protect Against Particles - Requirements, Testing, Marking

Based on the evaluation of test reports and internal quality control audit reports according to EN 149+A1:2009 and Personal Protective Equipment Regulation (EU) 2016/425 Annex VII (Module C2). This certificate implies that the manufactured products show below are in conformance with the approved EU Type Examination model and meets the requirements of the regulation. The details of compliance is given in technical report numbered **2163-PPE-640/01**

Product Definition

Model	Class	EU Type Examination Certificate		
		Serial Nr.	Date	Issuing NB Nr.
YD-002	FFP2	2163-PPE-639	28/04/2020	2163

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9**.
- Taking all measures necessary so that the manufacturing process and its monitoring ensure the homogeneity of production and conformity of the manufactured PPE with the type described in the EU type examination certificate.

This certificate is issued on **28/04/2020** and will be valid for one year, until **27/04/2021** if the manufacturer makes no major change in the product designs and manufacturing processes affecting the product performance on the essential health and safety requirement.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

The validity of this certificate can be verified online.

UNIVERSAL

UNIVERSAL
CERTIFICATION

NB 2163

EU TYPE EXAMINATION CERTIFICATE

Certificate Nr: 2163-PPE-639

Respiratory protective devices, filtering half masks to protect against particles manufactured by

Guangdong YIDAO Medical Technology Co., LTD.

Room 302, Building 2, No. 1, Lane 1, Xiju Road, Hengli, Dongguan City, Guangdong Province, P. R. CHINA

are tested and evaluated according to

EN 149:2001+A1:2009 Respiratory Protective Devices - Filtering Half Masks To Protect Against Particles - Requirements, Testing, Marking

Based on the type examination conducted with the evaluation of test reports, technical file according to Personal Protective Equipment Regulation (EU) 2016/425 Annex 5, it is approved that the product meets the requirements of the regulation. The details of essential requirement compliance is given in technical report numbered **2163-PPE-640.**

Product Definition

Brand Name: YPHD **Model:** YD-002

Filtering half mask

Total Inwards Leakage: Class – FFP2

Here by the manufacturer is allowed to use notified body number (2163) and can fix CE mark, as shown below, on the Category III product models given above, with;

- Issuing an appropriate EU Declaration of Conformity according to **Personal Protective Equipment Regulation (EU) 2016/425 Annex 9**.
- Ongoing successful performance in fulfilment of the requirements set out in Personal Protective **Equipment Regulation (EU) 2016/425** and harmonised standards, ensured by assessments based on **Annex 7 (Module C2) or Annex 8 (Module D)** of the regulation no later than 1 year from the beginning of serial production

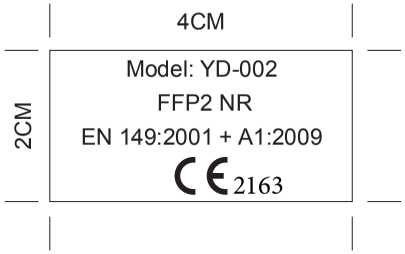
This certificate is initially issued on **28/04/2020** and will be valid for 5 years if there is no change in the relevant harmonised standard affecting the essential health and safety requirements.

CE
2163

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

The validity of this certificate can be verified online.

Necip Fazıl Bulvarı Keyap Sitesi E2 Blok No:44/84 Yukarı Dudullu Ümraniye - İSTANBUL - TURKEY T:+90 216 455 80 80
UNIVERSALCERT.COM


4CM
2CM
Model: YD-002
FFP2 NR
EN 149:2001 + A1:2009
CE 2163

MASCARILLA ANTIPARTíCULAS
ANTI-PARTICLE MASK
MASQUE ANTI-PARTICULES
MASCHERINA ANTIPARTICELLE
MÁSCARAS ANTI-PARTÍCULAS

vitalvida PHARMA

REF YD-002 **LOT** 32006334 **MOD** 6852

FFP2 NR

<80% -30 ° + 40°

2022-06

2020-06

CE 2163

EPI categoría III / PPE category III / EPI catégorie III / DPI categoria 2 / EPI categoria III

Estas macarillas antipartículas están ensayadas y con marcado CE2163 según EN 149:2001+A1:2009 y Regulación (UE) 2016/425. Declaración de conformidad disponible en:
These anti-particle masks are tested and CE2163 marked according to EN 149: 2001 + A1: 2009 and Regulation (EU) 2016/425. Declaration of conformity available at:
Ces masques anti-particules sont testés et marqués CE2163 selon EN 149: 2001 + A1: 2009 et Règlement (UE) 2016/425. Déclaration de conformité disponible sur:
Queste mascherine antiparticelle sono testate e marcate CE2163 secondo EN 149:2001+A1:2009 e Regolamento (UE) 2016/425. Dichiarazione di conformità disponibile su:
Estas máscaras anti-partículas são testadas e marcadas com CE2163 de acordo com EN 149:2001+A1:2009 e Regulação (UE) 2016/425. Declaração de conformidade disponível em:

https://www.joccashop.com/content/doc_mascarilla_anti_particula_FFP2YD-002.

Importado por:/ Imported by: C/Tarraca, nº 12 (Pol.Plaza)
Importé par:/Importato da: 50197 Zaragoza, Espanha
QUALIMAX INTERNATIONAL B-50152461

Guangdong Yidao Medical Technology Co., Ltd
Room 302, Building 2, No.1, Lane 1, Xiju Road, Hengli,
Dongguan City, Guangdong Province, P.R. China

8 435253 567710

Fabricado en RPC / Made in RPC /Fabriqué en RPC/Fabricado na RPC

ADVERTENCIA
Lea y comprenda antes de usar las siguientes indicaciones
1.- Una mascarilla debidamente seleccionada es esencial para proteger su salud. Antes de usar este o cualquier otro producto, consulte a un Higienista Industrial o un Profesional de Seguridad Ocupacional para determinar su idoneidad para el uso previsto. Este producto no protegerá contra vapores, gases o vapores, no lo use en operaciones de pintura en aerosol.
2.- No utilizar en operaciones de arenado.
3.- Este producto no suministra oxígeno. Use esta mascarilla solo en áreas bien ventiladas que contengan suficiente oxígeno (18% de oxígeno) para no poner en riesgo su vida
4.- No lo use cuando las concentraciones de contaminantes son desconocidas o inmediatamente peligrosas para la vida.
5.- Abandone el área de trabajo de inmediato si :
a) la respiración se vuelve difícil, o
b) se producen mareos u otros signos de angustia.
6.-Si el usuario tiene alguna enfermedad o trastorno, consulte a un médico con licencia para determinar la idoneidad de uso.
7.- El vello facial y ciertas características faciales pueden impedir el uso efectivo de este producto.
8.- Utilice la mascarilla sólo de acuerdo con las instrucciones, etiquetas y limitaciones relacionadas con este producto.
9.- No altere ni modifique este producto de ninguna manera.
10.- Siga las instrucciones del fabricante para ajustar la mascarilla a la cara.
11.- Mantenga las mascarillas en su embalaje lejos de la luz solar directa hasta su uso.
12.- Estas mascaras de filtración no deben usarse en alambiques, tanques, espacios cerrados ni en ninguna circunstancia en la que pueda haber presencia de gas, o en atmósferas deficientes en oxigeno.
13.-Para uso sólo contra aerosoles sólidos.
14.- Esta es una mascarilla de un solo uso. Deseche la mascarilla usada después de un solo uso (no más de 8 horas)
LIMITACIONES
1.- POLVO con un NEP (Nivel de exposición permisible) no inferior a 0.05 miligramos por metro cúbico de aire o 2 millones de partículas por pie cúbico de aire. Estos incluyen, entre otros, polvo de carbón, algodón, cadmio, cromo, plomo, manganeso, aluminio, harina, mineral de hierro y sílice libre que resulta principalmente de la desintegración de un sólido tal como acuerista en la minería, extracción, trituración, molienda o procesamiento general de minerales y otros materiales.
2.- Para uso solo contra aerosoles sólidos y a base de agua. Los aerosoles a base de agua son aquellos producidos a partir de soluciones y/ o suspensiones de materiales en partículas en el agua de modo que el único contaminante en el lugar de trabajo se atribuya a este material sólido.
3.- Esta mascarilla no es adecuada para desinfectar o limpiar.
ALMACENAMIENTO Y VIDA ÚTIL
Las mascarillas deben colocarse en un recipiente y almacenarse en una atmósfera limpia, fresca y seca para garantizar que estén protegidos del polvo, productos químicos, humedad, calor excesivo y luz solar directa. El incumplimiento de estos requisitos puede afectar el rendimiento y la vida útil del producto.
LIMPIEZA Y MANTENIMIENTO
No se requiere mantenimiento.

WARNING
Before using the mask read and follow the below recommendations:
1.- A properly selected mask is essential to protect your health. Before using this or any other product, consult an Industrial Hygienist or Occupational Safety Professional to determine its suitability for its intended use.
This product will not protect against vapours or gases. Do not use in spray painting operations.
2.- Do not use in sandblasting operations.
3.- This product does not supply oxygen. Use this mask only in well-ventilated areas that contain enough oxygen (18% oxygen) to avoid life-threatening.
4.- Do not use it when the concentrations of pollutants are unknown or immediately dangerous to life.
5.- Leave the work area immediately if:
a) breathing becomes difficult, or
b) dizziness or other signs of distress occur.
6.-If the user has any disease or disorder, consult a licensed physician to determine suitability for use.
7.- Facial hair and certain facial characteristics can prohibit the effective use of this product.
8 - Use only in accordance with the instructions, labels and limitations related to this product.
9 - Do not alter or modify this product in any way.
10.- Follow the manufacturer's instructions to fit the mask to your face.
11.- Keep the masks in their original packaging and away from direct sunlight until use.
12.- These filter masks must not be used in alembics, tanks, closed spaces or in any circumstance in which gas may be present or in oxygen deficient atmospheres.
13.-For use against solid aerosols only.
14.- This is a single-use mask. Discard used mask after single use (no more than 8 hours).
LIMITATIONS
1.- DUST with a PEN (Permissible Exposure Level) of not less than 0.05 milligrams per cubic meter of air or 2 million particles per cubic foot of air. These include, but are not limited to, carbon dust, cotton, cadmium, chromium, lead, manganese, aluminium, flour, iron minerals and silica are that results primarily from the disintegration of a solid such as would occur in mining , crushing, milling, or general processing of minerals and other materials.
2.- For use only against solid and water-based aerosols. Aerosols based on water are those produced from solutions and / or suspensions of particulate materials in the water so that the only contaminant in the workplace is attributed to this solid material.
3.- This mask is not suitable for disinfecting or cleaning.
STORAGE AND SHELF LIFE
Masks should be placed in a container and stored in a clean, cool and dry atmosphere to ensure that they are protected from dust, chemicals,
humidity, excessive heat and direct sunlight. Failure to comply with these requirements can affect performance and the shelf life of the product.
CLEANING AND MAINTENANCE
No maintenance required.

AVERTISSEMENTS:
Lisez attentivement les instructions suivantes :
1.- Un masque correctement sélectionné est essentiel pour protéger votre santé. Avant d'utiliser ce produit ou tout autre produit, consultez un professionnel de l'hygiène industrielle ou de la sécurité au travail pour déterminer votre aptitude à l'utilisation prévue.
Ce produit ne protégera pas contre les gaz ou les vapeurs, ne pas l'utiliser dans les opérations de peinture d'aérosol.
2.- Ne pas utiliser dans les opérations de sablage.
3.- Ce produit ne fournit pas d'oxygène. Utilisez ce masque uniquement dans les zones bien ventilées qui contiennent de l' oxygène afin de ne pas mettre votre vie en danger.
4.- Ne pas utiliser lorsque les concentrations d' agents contaminants sont inconnus ou dangereusement létales.
5.- Quitter immédiatement l'aire de travail si :
a) la respiration devient difficile
b) des étourdissements ou d'autres signes de détresse se produisent.
6.-Si l'utilisateur a une maladie ou un trouble, consultez un médecin autorisé pour déterminer la pertinence de l'utilisation.
7.- Les poils du visage et certaines caractéristiques faciales peuvent interdire l'utilisation efficace de ce produit.
8 - Utilisez uniquement conformément aux instructions, étiquettes et limitations liées à ce produit.
9.- Ne pas modifiez le produit de quelque façon que ce soit.
10.- Suivez les instructions du fabricant pour ajuster le masque au niveau du visage.
11.- Gardez les masques dans leur emballage loin de la lumière directe du soleil jusqu'à leur utilisation.
12.- Ces masques de filtration ne doivent pas être utilisés dans les alambics, les réservoirs, les espaces clos ou dans toutes les circonstances où le gaz peut être présent, ou dans des atmosphères déficientes en oxygène.
13.-Pour une utilisation uniquement contre les aérosols solides.
14.- Il s'agit d'un masque à usage unique. Disposer du masque usagé après une seule utilisation (pas plus de 8 heures)

LIMITATIONS:
1.- POUSSIÈRE avec un NEP (niveau d'exposition admissible) pas moins de 0,05 milligramme par mètre cube d'air ou 2 millions de particules par pied cube d'air. Cela induit notamment , la poussière de charbon, le coton, le cadmium, le chrome, le plomb, le manganèse, l'aluminium, la farine, le minerai de fer et silice libre résultant principalement de la désintégration d'un solide comme dans l'exploitation minière, l'extraction, le broyage, le broyage ou le traitement général des minéraux et d'autres matériaux.
2.- Pour une utilisation uniquement contre les aérosols solides et à base d'eau. Les aérosols à base d'eau sont ceux produits à partir de solutions et/ou de suspensions de matières particuleuses dans l'eau de sorte que le seul contaminant en milieu de travail est attribué à ce matériau solide.
3.- Ce masque ne convient pas à la désinfection ou au nettoyage.
STOCKAGE ET DURÉE DE CONSERVATION
Les masques doivent être placés dans un récipient et entreposés dans une atmosphère propre, fraîche et sèche pour s'assurer qu'ils sont protégés contre la poussière, les produits chimiques,
l'humidité, la chaleur excessive et la lumière directe du soleil. Le non-respect de ces exigences peut affecter le rendement et la durée de vie du produit.
NETTOYAGE ET ENTRETIEN
Aucun entretien requis.

AVVERTENZE
Leggere attentamente le seguenti indicazioni prima dell'uso
1.- Selezionare e dovere la mascherina è essenziale per proteggere la propria salute. Questo prodotto non protegge da vapori, gas o vapore, non utilizzarlo per operazioni con vernice spray.
2.-Non utilizzare per operazioni di sabbiatura.
3.-Questo prodotto non fornisce ossigeno. Utilizzare questa mascherina solo in aree ben ventilate che contengono abbastanza ossigeno (18% di ossigeno) per evitare di mettere a rischio la propria vita.
4.-Non utilizzare quando le concentrazioni di contaminanti sono sconosciute o di pericolo imminente per la vita.
5.-Abbandonare immediatamente l'area di lavoro se a) la respirazione diventa difficile, o B) si verificano capogiri, o altri segni di sopostarza. Se l'utente soffre di qualche tipo di malattia o disturbo, consultare il medico per determinare l'idoneità all'uso.
6.-Se l'utente soffre di qualche tipo di malattia o disturbo, consultare il medico per determinare l'idoneità all'uso.
7.-I peli del viso e alcune caratteristiche del volto possono limitare l'efficacia d'uso di questo prodotto.
8.- Utilizzare solo in conformità con le istruzioni d'uso, etichetta e limitazioni relative a questo prodotto.
9.- Non alterare o modificare questo prodotto in alcun modo.
10.- Seguire le istruzioni del produttore per adattare la maschera al viso
11.- Tenere le maschere nella loro confezione lontano dalla luce diretta del sole fino al momento dell'uso
12.- Queste maschere filtranti non devono essere utilizzate in distillerie, cisterne, spazi confinati o in qualsiasi circostanza in cui possa essere presente gas o in ambienti carenti di ossigeno.
13.- Da utilizzare solo contro aerosol solidi.
14.- Questa è una mascherina monouso. Gettare la mascherina usata dopo ogni singolo uso (non più di 8 ore).
LIMITAZIONI
1.- POLVERI con un Livello di Esposizione Consentito non inferiore a 0,05 milligrammi per metro cubo di aria o 2 milioni di particelle per piede cubico di aria. Queste includono, tra altre, polvere di carbone, cotone, cadmio, cromo, piombo, manganese, alluminio, farina, minerale metallico e silice libera che deriva principalmente dalla disintegrazione di un solido come si verificherebbe nel settore minerario, estrazione, frantumazione, macinazione o lavorazione generale di minerali e altri materiali.
2.- Da utilizzare solo contro aerosol solidi e a base di acqua. Gli aerosol a base di acqua sono quelli prodotti da soluzioni e / o sospensioni di materiali con particelle nell'acqua in modo che l'unico contaminante sul posto di lavoro sia attribuito a questo materiale solido.
3.- Questa mascherina non è adatta per la disinfezione o la pulizia.

CONSERVAZIONE E VITA UTILE
Le mascherine devono essere disposte in un contenitore e conservate in un luogo pulito, fresco e asciutto per garantire che siano protette da polvere, sostanze chimiche,
umidità, calore eccessivo e luce solare diretta. La mancata osservanza di questi requisiti può influire sulle prestazioni e sulla vita utile del prodotto.
PULIZIA E MANUTENZIONE
Non è richiesta manutenzione.

ADVERTÊNCIA
Leia atentamente as seguintes indicações antes de usá-lo:
1.-Uma máscara devidamente selecionada é essencial para proteger a sua saúde. Antes de usar este ou qualquer outro produto, consulte a um Higienista Industrial ou um Profissional de Segurança Ocupacional para determinar a eficácia para o uso previsto. Este produto não protegerá contra vapores ou gases, por tanto, não usá-lo em trabalhos de pintura com aerossóis.
Este produto não protegerá contra vapores ou gases, por tanto, não usá-lo em trabalhos de pintura com aerossóis.
2.- Não deverá ser utilizado em jateamentos de areia.
3.-Este produto não fornece oxigênio. Use esta máscara somente em áreas bem ventiladas que contenham suficiente oxigênio (18% de oxigênio) para não colocar sua vida em risco.
4.- Não indicada para concentrações de contaminantes desconhecidos ou imediatamente perigosas para a saúde ou para a vida.
5.- Abandone imediatamente a área de trabalho se: a) respiração torna-se difícil ou
b.) Se produz náuseas ou outros sintomas de angústia
6.- Se o usuário tiver alguma doença ou transtorno, consulte previamente o seu médico para determinar a eficácia do uso.
7.- Os pelos e certas características faciais podem dificultar a eficiência do uso deste produto.
8.-Utilize somente de acordo com as instruções, etiquetas e limitações relacionadas com este produto.
9.- Não altere nem modifique este produto de nenhuma maneira.
10.-Siga as instruções do fabricante para ajustar a máscara ao rosto.
11.- Mantenha a máscara na embalagem longe da luz solar direta até o seu uso.
12.- Estas máscaras de filtração não devem ser usadas em alambiques, tanques, espaços fechados nem em qualquer lugar ou circunstâncias nas que possam haver presença de gases ou em atmosferas deficientes de oxigênio.
13.- Somente para uso em contra de aerossóis sólidos.
14.- Esta é uma máscara de um único uso. Deite-a fora depois de usada (não deve ser usada mais de 8 horas).
LIMITAÇÕES
1.-PÓ com um NEP (Nível de exposição permissível) não inferior a 0,05 miligramos por metro cúbico de ar ou 2 milhões de partículas por pé cúbico de ar. Isto inclui, entre outros, pó de carvão, algodão, cádmio, cromo, chumbo, manganês, alumínio, farinha, mineral de ferro e sílica livre que resulta principalmente da desintegração de um sólido, como ocorreria na mineração, moagem ou processamento geral de minerais e outros materiais.
2.-Para uso somente contra aerossóis sólidos e a base d'água. Os aerossóis a base d'água são aqueles produzidos a partir de soluções e/ou suspensões de materiais em partículas na água de modo que o único contaminante no lugar de trabalho se atribua a este material sólido.
3.- Esta máscara não é adequada para desinfectar ou limpar.
ARMAZENAGEM E VIDA ÚTIL
As máscaras devem ser colocadas em um recipiente e ser armazenadas em uma atmosfera limpa, fresca e seca para garantir que estejam protegidas do pó, produtos químicos, humidade, calor excessivo e luz solar direta. O incumprimento destes requisitos podem afetar o rendimento e a vida útil do produto.
LIMPEZA E MANUTENÇAO
Não se necessita manutenção

vitalvida PHARMA

MASCARILLA ANTIPARTíCULAS
ANTI-PARTICLE MASK
MASQUE ANTI-PARTICULES
MASCHERINA ANTIPARTICELLE
MÁSCARAS ANTI-PARTÍCULAS

REF YD-002 **LOT** 32006334 **MOD** 6852

FFP2 NR

NON-MEDICAL KN95 MASK

Packing : 460 pcs/CTN
CTN Size : 58 x 32 x 29 cm
N.W.: 3 KGS / CTN
G.W.: 3.6 KGS / CTN

Estas mascarillas antipartículas están ensayadas y con marcado CE2163 según EN149:2001+A1:2009 y Regulación (UE) 2016/425. Declaración de conformidad disponible en: https://www.joccashop.com/content/doc_mascarilla_anti_particula_FFP2YD-002.
These anti-particle masks are tested and CE2163 marked according to EN 149: 2001 + A1: 2009 and Regulation (EU) 2016/425. Declaration of conformity available at: https://www.joccashop.com/content/doc_mascarilla_anti_particula_FFP2YD-002.
Ces masques anti-particules sont testés et certifiés EN 149:2001-A1:2009 /Régulation (EU) 2016/425. Déclaration de conformité disponible sur : https://www.joccashop.com/content/doc_mascarilla_anti_particula_FFP2YD-002.
Queste mascherine antiparticelle sono testate e marcate CE2163 secondo EN149:2001+A1:2009 e Regolamento (UE) 2016/425. Dichiarazione di conformità disponibile su: https://www.joccashop.com/content/doc_mascarilla_anti_particula_FFP2YD-002.
Estas máscaras anti-partículas são testadas e marcadas com CE2163 de acordo com EN149:2001+A1:2009 e Regulação (UE) 2016/425. Declaração de conformidade disponível em: https://www.joccashop.com/content/doc_mascarilla_anti_particula_FFP2YD-002.

EPI categoría III / PPE category III / EPI catégorie III / DPI categoria III / EPI categoria III

Importado por:/ Imported by:/ Importé par:/Importato da:

QUALIMAX INTERNATIONAL
C/Tarraca, nº 12 (Pol.Plaza)
50197 Zaragoza, Espanha
B-50152461

Guangdong Yidao Medical Technology Co., Ltd
Room 302, Building 2, No.1, Lane 1, Xiju Road, Hengli, Dongguan City, Guangdong Province, P.R. China

CE 2163

Fabricado en RPC / Made in RPC /Fabriqué en RPC/Fabricado na RPC

<80%

-30 ° +40°

2022-06

2020-06

18435253567717

TEST REPORT

EN 149:2001 + A1:2009

Particle Filtering Half Masks

Client:	Guangdong YIDAO Medical Technology Co., LTD.
Manufacturing Address:	Room 302, Building 2, No. 1, Lane 1, Xiju Road, Hengli, Dongguan City, Guangdong Province, P.R. CHINA
Model (s):	YD-002 FFP2 NR without valve
Sample received on:	April 07, 2020
Report Number:	NPT/20040712669
Elaborated by:	Ashley Madison
Place and date of issue:	Sheridan, WY April 25, 2020

Dr. Joseph Andrew, Ph.D.
Head of Testing Laboratory

Testing Laboratory: 1309 Coffeen Avenue STE 1200, Sheridan, WY, 82801, USA
Tel.:307-207-4535 Fax: 307-207-4535 E-mail: mdd@nptesting.com www.nptesting.com

TEST RESULT DETAILS (EN 149:2001 + A1:2009)

7.4 Packaging (EN 149:2001 + A1:2009 clause 8.2)	
The masks were not packaged as offered for sale. Manufacturer to certify regarding the final packaging to be used.	*NAs*
The masks were packaged in sealed plastic bags, in larger plastic bags inside a large cardboard box that gave some protection against mechanical damage or contamination before use.	*Passed*

7.5 Material (EN 149:2001 + A1:2009 clause 8.2, 8.3.1, 8.3.2)	
The materials used were able to withstand handling and wear during the limited laboratory testing carried out.	*Passed*
The effect on materials from "in-use" environmental factors could not be evaluated during laboratory tests. Manufacturer to certify regarding such factors.	*NAs*
Samples were conditioned in accordance with 8.3.1. None of the specimens conditioned suffered mechanical failure or collapse.	*Passed*
Samples were conditioned in accordance with 8.3.2. None of the specimens conditioned suffered collapse.	*Passed*

7.6 Cleaning and Disinfecting (EN 149:2001 + A1:2009 clause 8.4, 8.5, 8.11)	
If the particle filtering half mask is designed to be re-usable, the materials used shall withstand the cleaning and disinfecting agents and procedures to be specified by the manufacturer. With reference to 7.9.2, after cleaning and disinfecting the re-usable particle filtering half mask shall satisfy the penetration requirement of the relevant class.	*N/A*

7.7 Practical Performance (EN 149:2001 + A1:2009 clause 8.4)	
See tested reference number PPT-001	*Passed*

7.8 Finish of Parts (EN 149:2001 + A1:2009 clause 8.2)	
None of the specimens used in laboratory testing showed evidence of sharp edges or burrs.	*Passed*

7.9.1 Total Inward Leakage (EN 149:2001 + A1:2009 clause 8.5)	
See tested reference number TIL-001	*Passed*

7.9.2.a Penetration of Filter Material-Sodium Chloride (EN 149:2001 + A1:2009 clause 8.11 & EN 13274-7:2019)	
See tested reference number SCT-001	*Passed*
7.9.2.b Penetration of Filter Material-Paraffin Oil (EN 149:2001 + A1:2009 clause 8.11 & EN 13274-7:2019)	
See tested reference number POT-001	*Passed*

7.10 Compatibility with skin (EN 149:2001 + A1:2009 clause 8.4, 8,5)	
No problems were encountered during practical performance testing.	*Passed*
No problems were encountered during total inward leakage testing.	*Passed*
The likelihood of materials in contact with the skin causing irritation or other adverse effect on health was not assessed. Manufacturer to certify.	*NAs*

Testing Laboratory: 1309 Coffeen Avenue STE 1200, Sheridan, WY, 82801, USA
Tel.:307-207-4535 Fax: 307-207-4535 E-mail: mdd@nptesting.com www.nptesting.com

7.11 Flammability (EN 149:2001 + A1:2009 clause 8.6)	
See tested reference number FT-001	*Passed*

7.12 Carbon dioxide content of the inhalation air (EN 149:2001 + A1:2009 clause 8.7)	
See tested reference number CDT-001	*Passed*

7.13 Head harness (EN 149:2001 + A1:2009 clause 8.4, 8.5)	
The head harness was designed to allow the particle filtering half-mask to be donned and removed easily during limited practical performance and total inward leakage testing.	*Passed*
The head harness was adjustable and there were no adverse comments regarding security following limited practical performance and total inward leakage testing.	*Passed*
The product satisfied the total inward leakage requirements.	*Passed*

7.14 Field of vision (EN 149:2001 + A1:2009 clause 8.4)	
There were no adverse comments following practical performance tests.	*Passed*

7.15 Exhalation Valve (EN 149:2001 + A1:2009 clause 8.2, 8.3.4, 8.8, 8.9.1)	
Not applicable	*N/A*

7.16 Breathing Resistance (EN 149:2001 + A1:2009 clause 8.9)	
See tested reference number BRT-001	*Passed*

7.17 Clogging (EN 149:2001 + A1:2009 clause 8.9, 8.10)	
This is optional test and not desired by client.	*NAs*

7.18 Demountable Parts (EN 149:2001 + A1:2009 clause 8.2)	
No demountable parts	*N/A*

8.3 Conditioning	
See tested reference number CS-001	*Passed*

Passed	*Requirement satisfied.*
NCR	*Requirement not satisfied. Refer to the "Result details" section for more information.*
NAs	*Assessment not carried out.*
N/A	*Requirement not applicable.*

Conclusion:

Model	***Recommendation Level***
YD-002	*FFP2 NR*

Note: The results given in this Test Report apply only to the sample tested by our laboratory!

Testing Laboratory: 1309 Coffeen Avenue STE 1200, Sheridan, WY, 82801, USA
Tel.:307-207-4535 Fax: 307-207-4535 E-mail: mdd@nptesting.com www.nptesting.com

Test Standard: EN 149:2001+A1:2009 / EN 13274-5:2001
Name of tests: Conditioning of Samples
Reference no: CS-001

Simulated wearing treatment
Conditioning by simulated wearing treatment has been carried out by the following process. A breathing machine is adjusted to 25 cycles/min and 2,0 l/stroke. The particle filtering half mask was mounted on a Sheffield dummy head. For testing, a saturator is incorporated in the exhalation line between the breathing machine and the dummy head, the saturator being set at a temperature in excess of 37 °C to allow for the cooling of the air before it reaches the mouth of the dummy head. The air has been saturated at (37 ± 2) °C at the mouth of the dummy head.

In order to prevent excess water spilling out of the dummy's mouth and contaminating the particle filtering half mask the head has been inclined so that the water runs away from the mouth and is collected in a trap. The breathing machine was brought into operation, the saturator switched on and the apparatus allowed to stabilize. The particle filtering half mask under test has then been mounted on the dummy head. During the test time at approximately 20 min intervals the particle filtering half mask has been completely removed from the dummy head and refitted such that during the test period it is fitted ten times to the dummy head.

Temperature conditioning
Unless otherwise specified, the ambient temperature for testing has been between 16 °C and 32 °C and the temperature limits has been subject to an accuracy of ±1 °C.

In order to ensure that there is no thermal shock during the conditioning of the specimens, the temperature gradient has been less than 2 °C/min between phases at different temperatures, or between the beginning and the end of a thermal cycle.

Expose the particle filtering half masks to the following thermal cycle:
a) for 24 h to a dry atmosphere of (70 ± 3) °C;
b) for 24 h to a temperature of (-30 ± 3) °C; and allow to return to room temperature for at least 4 h between exposures and prior to subsequent testing. The conditioning has been carried out in a manner which ensures that no thermal shock occurs

Mechanical strength
The apparatus consists of a steel case (K) which is fixed on a vertically moving piston (S), capable of being lifted up 20 mm by a rotating cam (N) and dropping down onto a steel plate (P) under its own mass as the cam rotates. The mass of the steel case shall be more than 10 kg. The weight of the steel plate onto which the steel case falls should be (at least) 10 times the weight of the steel case. This may be achieved by bolting the base plate to a hard solid floor.

Test results:
The test results obtained are given in the tables as follows

No	*Conditioning Area*	*Samples Number*
1	Simulated wearing treatment	1-2-3-4-5-6 (As Received)
2	Temperature conditioning	7-8-9-10-11-12 (Sample after test of Mechanical Strength)
		13-14-15-16-17-18-19-20-21-22 (As Received)
3	Mechanical strength	7-8-9-10-11-12 (As Received)

Testing Laboratory: 1309 Coffeen Avenue STE 1200, Sheridan, WY, 82801, USA
Tel.:307-207-4535 Fax: 307-207-4535 E-mail: mdd@nptesting.com www.nptesting.com

Test Standard: EN 149:2001+A1:2009 / EN 13274-2:2001
Name of tests: Practical Performance Testing
Reference no: PPT-001

Test Purpose:
This test method is used to determine practical performance when its purpose is fitted by subjects during use in the simulated application, it subjectively evaluates certain features, characteristics and functions of the device that cannot be evaluated by experiments described in other standards.

Sampling method:
A total of two particle filtering half masks have been tested: two in the state as received.

Testing methods used:
A test method for determining practical performance in accordance with standard EN 13274-2:2001 + EN 149:2001 + A1:2009 clause 7.7/8.4

Test conditions:
The test has been carried out in a normally lit area with a temperature of 16 ° C to 32 ° C and a relative humidity of 30% to 80%. The actual temperature and humidity conditions and noise level have been recorded.

Test Principle:
A total of 2 particle filtering half masks have been tested: both as received. All tests have been carried out by two test subjects at ambient temperature and the test temperature and humidity have been recorded. Prior to the test there has been an examination to assure that the particle filtering half mask is in good working condition and that it can be used without hazard. For the test, persons have been selected who are familiar with using such or similar equipment.

Test Equipment:
A small basket (approximate volume = 8 l) with chippings or other suitable material from a hopper

Test Procedure:
General: During the tests the particle filtering half mask shall be subjectively assessed by the wearer and after the test, comments on the following shall be recorded: a) head harness comfort; b) security of fastenings; c) field of vision; d) any other comments reported by the wearer on request.

Walking test: The subjects wearing normal working clothes and wearing the particle filtering half mask shall walk at a regular rate of 6 km/h on a level course. The test shall be continuous, without removal of the particle filtering half mask, for a period of 10 min.

Work simulation test: The particle filtering half mask shall be tested under conditions which can be expected during normal use. During this test the following activities shall be carried out in simulation of the practical use of the particle filtering half mask. The test shall be completed within a total working time of 20 min. The sequence of activities is at the discretion of the test house. The individual activities shall be arranged so that sufficient time is left for the comments prescribed.
a) walking on the level with headroom of (1,3 ± 0,2) m for 5 min;
b) crawling on the level with headroom of (0,70 ± 0,05) m for 5 min;
c) filling a small basket (see Figure 1, approximate volume = 8 l) with chippings or other suitable material from a hopper which stands 1,5 m high and has an opening at the bottom to allow the contents to be shovelled out and a further opening at the top where the basket full of chippings is returned. The subject shall stoop or kneel as he wishes and fill the basket with chippings. He shall then lift the basket and empty the contents back into the hopper. This shall be done 20 times in 10 min.

Testing Laboratory: 1309 Coffeen Avenue STE 1200, Sheridan, WY, 82801, USA
Tel.:307-207-4535 Fax: 307-207-4535 E-mail: mdd@nptesting.com www.nptesting.com

Test results:
The test results obtained are given in the tables as follows

Number of sample: 39 (A.R), 40 (A.R)

Assessed elements	*Positive Assessment*	*Negative Assessment*	*Requirements in accordance with EN 149:2001+A1:2009*	*Assessment of Test Result Conformity / Nonconformity*
1. The face piece fitting	2	0	Filtering half masks should not have imperfections related to wearer's acceptance	Filtering half masks fulfill requirements of the standard EN 149:2001 + A1:2009 given in 7.7
2. Head harness comfort	2	0		
3. Security of fastenings	2	0		
4. Speech clearness	2	0		
5. Field of vision	2	0		
6. Materials compatibility with skin	2	0		No imperfections

Testing Laboratory: 1309 Coffeen Avenue STE 1200, Sheridan, WY, 82801, USA
Tel.:307-207-4535 Fax: 307-207-4535 E-mail: mdd@nptesting.com www.nptesting.com

Test Standard: EN 149:2001+A1:2009 / EN 13274-1:2001
Name of tests: Total Inward Leakage Testing
Reference no: TIL-001

Test Purpose:
This test method is used to determine the total inward leakage in respiratory protective devices.

Sampling method:
A total of ten particle filtering half masks have been tested: five in the state as received and five after temperature conditioning.

Testing methods used:
A test method for determining total inward leakage in accordance with standard EN 13274-1:2001 + EN 149:2001 + A1:2009 clause 7.9.1/8.5.

Test conditions:
The five test samples were conditioned in accordance with temperature conditioning.

Test Principle:
The total inward leakage has been tested using sodium chloride aerosol. Prior to the test there has been an examination to ensure that the particle filtering half mask is in good working condition and that it can be used without hazard.
For the test, persons has been selected who are familiar with using such or similar equipment. A panel of ten clean-shaven persons (without beards or sideburns) has been selected covering the spectrum of facial characteristics of typical users (excluding significant abnormalities). It is to be expected that exceptionally some persons cannot be satisfactorily fitted with a particle filtering half mask. Such exceptional subjects has not been used for testing particle filtering half masks.

Test Equipment:
The test atmosphere shall preferably enter the top of the enclosure through a flow distributor, and be directed downwards over the head of the test subject at a minimum flow rate of 0,12 m/s. The concentration of the test agent inside the effective working volume shall be checked to be homogeneous. The flow rate should be measured close to the subject's head. A level treadmill is required capable of working at 6 km/h.

Test Procedure:
Ask the test subjects to read the manufacturer's fitting information and if more than one size of particle filtering half mask is manufactured, ask the test subject to select the size deemed by him to be the most appropriate. If necessary the test supervisor shall show the test subjects how to fit the particle filtering half mask correctly in accordance with the fitting information. Inform the test subjects that if they wish to adjust the particle filtering half mask during the test they may do so. However if this is done, repeat the relevant section of the test, having allowed the system to resettle. The test subjects shall have no indication of the results as the test proceeds.

After fitting the particle filtering half mask, ask each test subject 'Does the mask fit?' If the answer is 'Yes', continue the test. If the answer is 'No', take the test subject off the panel, report the fact and replace with another test subject.

Testing Laboratory: 1309 Coffeen Avenue STE 1200, Sheridan, WY, 82801, USA
Tel.:307-207-4535 Fax: 307-207-4535 E-mail: mdd@nptesting.com www.nptesting.com

Test results:
The test results obtained are given in the tables as follows

Test Subject	*No of sample*	*Cond.*	*1. Walk (%)*	*Head side/ side (%)*	*Head up/down (%)*	*Talk (%)*	*2. Walk (%)*	*Mean (%)*
1	32	A.R.	4,93	5,21	4,88	5,10	4,77	4,98
2	33	A.R.	4,96	5,32	4,89	5,41	4,79	5,07
3	34	A.R.	4,85	5,62	4,95	5,68	4,91	5,20
4	35	A.R.	4,77	5,56	4,75	5,30	4,66	5,01
5	36	A.R.	4,82	5,52	4,77	5,66	4,72	5,10
6	16	T.C.	5,11	5,41	5,11	5,34	5,10	5,21
7	17	T.C.	5,25	5,49	5,25	5,49	5,15	5,33
8	18	T.C.	5,29	4,32	5,16	5,34	5,16	5,05
9	19	T.C.	5,34	5,22	5,35	5,42	5,21	5,31
10	20	T.C.	5,24	5,32	5,37	5,38	5,26	5,31
Maximum permitted			All individual exercise results were not greater than 11 %					Not greater than 8%

Requirements in accordance with EN 149:2001+A1:2009	*Assessment of Test Result Conformity / Nonconformity*
at least 46 out of the 50 individual results shall be not greater than 25 % for FFP1 11 % for FFP2 5 % for FFP3 and at least 8 out of the 10 individual wearer means shall be not greater than 22 % for FFP1 8 % for FFP2 2 % for FFP3	Passed Filtering half masks fulfil requirements of the standard EN 149:2001 + A1:2009 given in 7.9.1 in range of the first, the second and the third protection class (FFP1, FFP2, FFP3)

Testing Laboratory: 1309 Coffeen Avenue STE 1200, Sheridan, WY, 82801, USA
Tel.:307-207-4535 Fax: 307-207-4535 E-mail: mdd@nptesting.com www.nptesting.com

Test Standard: EN 149:2001+A1:2009 / EN 13274-7:2019
Name of tests: Penetration of filter material Sodium Chloride Testing
Reference no: SCT-001

Test Purpose:
This test method is used to measure that the penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1 in 7.9.2.

Sampling method:
A total of nine particle filtering half masks have been tested: three in the state as received, three the simulated wearing treatment and three samples after the mechanical strength test and temperature conditioning.

Testing methods used:
A test method for determining penetration of filter material sodium chloride testing in accordance with standard EN 13274-7:2019 / EN 149:2001 + A1:2009 clause 7.9.2

Test conditions:
The six test samples were conditioned in accordance with mechanical strength test and temperature conditioning, simulated wearing treatment.

Test Principle:
The Sodium Chloride Aerosol Challenge test is able to determine filtration efficiency measurements up to 99.999% l.
The sample is placed into the filter holder. Cone or molded masks and respirators are mounted to a test fixture and sealed into a cylinder filter holder to ensure that the mask is properly sealed.
Samples are subjected to aerosolized NaCl. The concentration of NaCl is measured before and after impact with the sample. The amount of NaCl that passes through the sample is used to calculate the filtration efficiency of the sample.

Test Equipment:
The test equipment consists four modules sodium chloride aerosol generator flow control, filter test chamber, flame photometer aerosol detector. Sodium chloride aerosol is detected before and after the filtering device under test by flame photometry.

Test Procedure:
The device shall be mounted in a leak tight manner on a suitable adaptor and subjected to the test(s), ensuring that components of the device that could affect filter penetration values such as valves and harness attachment points are exposed to the challenge aerosol.
In order to carry out tests on the filtration efficiency of the filter material against particulates, a 1.0% NaCl solution based on demineralized water is used.
From the above solution using a Collison atomizer, an aerosol is generated with a particle diameter of 600 nm and an average concentration of 8 mg / m3
The aerosol is passed through the tested complete filtering half mask, sealed in the test chamber, with an air flow rate of 95 l / min. The test aerosol concentration is determined before and after the test sample using flame photometry. Comparison of determined concentrations allows to determine the filtration efficiency of the tested sample in the range from 0.00001% to 100%.

Test results:
The test results obtained are given in the tables as follows

No. of Sample	*Condition*	*Penetration of Sodium Chloride in accordance with EN 13274-7:2019 [%] Flow rate 95 l/min*	*Requirements in accordance with EN 149:2001+A1:2009*	*Assessment of Test Result Conformity / Nonconformity*
23	As received	3,82	FFP1 ≤ 20 % FFP2 ≤ 6 % FFP3 ≤ 1 %	Passed Filtering half masks fulfil the requirements of the standard EN 149:2001+A1:2009 given in 7.9.2 in range of the first and the second protection class (FFP1, FFP2)
24		3,76		
25		3,90		
1	Simulated wearing treatment	4,14		
2		4,16		
3		4,20		
7	Mechanical strength + Temperature conditioned	4,45		
8		4,78		
9		4,69		

Testing Laboratory: 1309 Coffeen Avenue STE 1200, Sheridan, WY, 82801, USA
Tel.:307-207-4535 Fax: 307-207-4535 E-mail: mdd@nptesting.com www.nptesting.com

Test Standard: EN 149:2001+A1:2009 / EN 13274-7:2019
Name of tests: Penetration of filter material Paraffin Oil Testing:
Reference no: POT-001

Test Purpose:
This test method is used to measure that the penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1 in 7.9.2.

Sampling method:
A total of nine particle filtering half masks have been tested: three in the state as received, three the simulated wearing treatment and three samples after the mechanical strength test and temperature conditioning.

Testing methods used:
A test method for determining penetration of filter material sodium chloride testing in accordance with standard EN 13274-7:2019 / EN 149:2001 + A1:2009 clause 7.9.2

Test conditions:
The six test samples were conditioned in accordance with mechanical strength test and temperature conditioning, simulated wearing treatment.

Test Principle:
An aerosol of paraffin oil droplets is generated by atomising paraffin oil. The concentration of this aerosol is measured before and after the filter under test by means of a light scattering aerosol photometer. Determinations have been possible in the range < 0.001% to 100% filter penetration.

Test Equipment:
The test equipment consists four modules paraffin oil mist aerosol generator flow control, filter test chamber, scattered light aerosol detector. The aerosol mass concentration and particle size distribution has been measured within the filter test chamber.

Test Procedure:
Tests on the efficiency of filtration against liquid particles are carried out using a paraffin oil mist generated using a CP 27 DAB paraffin oil atomizer heated to 1000C. The liquid aerosol thus generated has an average concentration of 20 mg / m3 and an average particle diameter of 400 nm. The aerosol thus generated is passed through the tested complete filtering half mask, sealed in the test chamber, with an air flow rate of 95 l / min.
The concentration of the test aerosol before and after the sample is determined by means of laser photometry. Comparison of determined concentrations allows to determine the filtration efficiency test sample for liquid aerosols in the concentration range from 0.0001% to 100%.

Test results:
The test results obtained are given in the tables as follows

No. of Sample	*Condition*	*Penetration of Paraffin Oil Mist in accordance with EN 13274-7:2019 [%] Flow rate 95 l/min*	*Requirements in accordance with EN 149:2001+A1:2009*	*Assessment of Test Result Conformity / Nonconformity*
26	As received	4,27	FFP1 ≤ 20 % FFP2 ≤ 6 % FFP3 ≤ 1 %	Passed Filtering half masks fulfil the requirements of the standard EN 149:2001+A1:2009 given in 7.9.2 in range of the first and the second protection class (FFP1, FFP2)
27		4,20		
28		4,16		
4	Simulated wearing treatment	3,94		
5		3,88		
6		3,76		
10	Mechanical strength + Temperature conditioned	4,26		
11		4,27		
12		4,36		

Testing Laboratory: 1309 Coffeen Avenue STE 1200, Sheridan, WY, 82801, USA
Tel.:307-207-4535 Fax: 307-207-4535 E-mail: mdd@nptesting.com www.nptesting.com

Test Standard: EN 149:2001+A1:2009 / EN 13274-4:2001
Name of tests: Flammability Testing
Reference no: FT-001

Test Purpose:
This test method is used to measure that the materials used in the device are not dangerous for the person using the device and do not possess highly flammable nature.

Sampling method:
A total of four particle filtering half masks have been tested: two in the state as received and two after temperature conditioning.

Testing methods used:
A test method for determining Flammability in accordance with standard EN 13274-4:2001 + EN 149:2001 + A1:2009 clause 7.11/8.6.

Test conditions:
The two test samples were conditioned in accordance with temperature conditioning.

Test Principle:
The filtering face pieces subjected to the test, are passed one by one through a flame with a temperature of 800°C +/- 50°C and at a speed of 6 cm/s. The respirators must not go on burning for more than 5 s after removal from the flame.

Test Equipment:
The test rig consists mainly of a propane cylinder with flow control device, pressure gauge, flash back arrester, specimen support, rotation motor with speed controller, and burner. The burner has been either be in accordance with 6.2 or with ISO 6941. The purity of the propane has been a minimum of 95 %.

Test Procedure:
The face piece is put on a metallic dummy head which is motorized such that it describes a horizontal circle with a linear speed, measured at the tip of the nose, of (60 ± 5) mm/s. The head is arranged to pass over a propane burner the position of which can be adjusted. By means of a suitable gauge, the distance between the top of the burner, and the lowest part of the face piece (when positioned directly over the burner) shall be set to (20 ± 2) mm.

With the head turned away from the area adjacent to the burner, the propane gas is turned on, the pressure adjusted to between 0,2 bar and 0,3 bar and the gas ignited. By means of a needle valve and fine adjustments to the supply pressure, the flame height had been set to (40 ± 4) mm. This is measured with a suitable gauge.

The temperature of the flame measured at a height of (20 ± 2) mm above the burner tip by means of a 1,5 mm diameter mineral insulated thermocouple probe, shall be (800 ± 50) °C. Failure to meet the temperature requirement indicates that a fault such as a partially blocked burner exists. This had been rectified before testing. The head is set in motion and the effect of passing the face piece once through the flame has been noted.

The test has been repeated to enable an assessment to be made of all materials on the exterior of the device. Any one component has been passed through the flame once only

Test results:
The test results obtained are given in the tables as follows

No. of Sample	*Condition*	*Visual inspection*	*Requirements in accordance with EN 149:2001+A1:2009*	*Assessment of Test Result Conformity / Nonconformity*
32	As received	1,4	Filtering half mask shall not burn or not continue to burn for more than 5 s after removal from the flame	Passed Filtering half masks fulfill requirements of the standard EN 149:2001 + A1:2009 given in 7.1
33		1,3		
21	Temperature conditioned	1,2		
22		1,1		

Testing Laboratory: 1309 Coffeen Avenue STE 1200, Sheridan, WY, 82801, USA
Tel.:307-207-4535 Fax: 307-207-4535 E-mail: mdd@nptesting.com www.nptesting.com

Test Standard: EN 149:2001+A1:2009 / EN 13274-6:2001
Name of tests: Carbon dioxide content of the inhalation air Testing
Reference no: CDT-001

Test Purpose:
This test method is used to determine carbon dioxide content of the inhalation air.

Sampling method:
A total of three particle filtering half masks have been tested: all three in the state as received.

Testing methods used:
A test method for determining carbon dioxide content of the inhalation air in accordance with standard EN 13274-6:2001 + EN 149:2001 + A1:2009 clause 7.12/8.7.

Test conditions:
The atmosphere where the temperature is from 16 ° C to 32 ° C and the relative humidity is 20% to 80%.

Test Principle:
The device is attached to the Sheffield mannequin head / body as described in the device standard; In the case of complete hardware testing, an air supply is operated under the manufacturer's lowest conditions, unless otherwise specified in the relevant standard. Air containing carbon dioxide at a certain concentration is supplied from the respirator to the mannequin head / body at a given flow rate. The inhaled air is analysed for its carbon dioxide content.
The measured carbon dioxide level provides information on the assessment of the "dead volume" of the facial protective part rather than a "real" measurement of the carbon dioxide level in the inhaled air.

Test Equipment:
The test rig consists Breathing apparatus, Auxiliary lung, Solenoid valve, Sheffield Mannequin head, Non-return valve, Sampling pipe for breathing air, Flow meter, Carbon dioxide absorber, Balancer, Carbon dioxide supply, Carbon dioxide analyzer

Test Procedure:
The apparatus subjects the particle filtering half mask to a respiration cycle by the breathing machine. For this test the particle filtering half mask has been fitted securely in a leak-tight manner but without deformation to a Sheffield dummy head. Air has been supplied to it from a breathing machine adjusted to 25 cycles/min and 2,0 l/stroke and the exhaled air has a carbon dioxide content of 5 % by volume. If the design of the test equipment causes a CO2 build-up a CO2 absorber has been used in the inhalation branch between solenoid valve and breathing machine. The CO2 is fed into the breathing machine via a control valve, a flowmeter, a compensating bag and two non-return valves. Immediately before the solenoid valve a small quantity of exhaled air is preferably continuously withdrawn through a sampling line and then fed into the exhaled air via a CO2 analyser.

To measure the CO2 content of the inhaled air, 5 % of the stroke volume of the inhalation phase of the breathing machine is drawn off at the marked place by an auxiliary lung and fed to a CO2 analyser. The total dead space of the gas path (excluding the breathing machine) of the test installation should not exceed 2000 ml. Measure the carbon dioxide content of the inhaled air and record continuously. Test conditions are ambient atmospheric conditions. The ambient carbon dioxide level is measured 1 m in front of and level with the tips of the nose of the dummy head. The ambient level is measured once a stabilized level for carbon dioxide in the inhalation air has been attained. Alternatively, the ambient level of carbon dioxide may be measured at the sampling tube with the carbon dioxide supply turned off. Results are deemed acceptable only if the measured value of the ambient level of carbon dioxide is less than 0,1 %

Test results:
The test results obtained are given in the tables as follows;

No. of Sample	*Condition*	*CO_2 content of the inhalation air [%] by volume*	*An average CO_2 content of the inhalation air [%] by volume*	*Requirements in accordance with EN 149:2001+A1:2009*	*Assessment of Test Result Conformity / Nonconformity*
41	As received	0,91	0,89	CO_2 content of the inhalation air shall not exceed an average of 1,0% by volume	Passed Filtering half masks fulfill requirements of the standard EN 149:2001 + A1:2009 given in 7.12
42		0,83			
43		0,92			

Testing Laboratory: 1309 Coffeen Avenue STE 1200, Sheridan, WY, 82801, USA
Tel.:307-207-4535 Fax: 307-207-4535 E-mail: mdd@nptesting.com www.nptesting.com

Test Standard: EN 149:2001+A1:2009 / EN 13274-3:2001
Name of tests: Breathing Resistance Testing-Inhalation/Exhalation Resistance
Reference no: BRT-001

Test Purpose:
This test method is used to measure that inhalation and exhalation resistance values.

Sampling method:
A total of nine particle filtering half masks have been tested: three in the state as received, three the simulated wearing treatment and three samples after the temperature conditioning.

Testing methods used:
A test method for determining inhalation and exhalation resistance testing in accordance with standard EN 13274-3:2001 / EN 149:2001 + A1:2009 clause 7.16

Test conditions:
The six test samples were conditioned in accordance with temperature conditioning and simulated wearing treatment.

Test Principle:
The device is placed on a support as specified in the relevant device standard and connected to the respirator adjusted to the respiratory volume at the specified minute.
While respiratory resistance is reported; If the pressure inside the facial part is negative compared to atmospheric pressure during the inhalation resistance test, no sign is put in front of the result, and when the relative pressure inside the face protector is positive, a "+" sign is placed in front of the result.

Test Equipment:
A sinus-shaped breathing apparatus. Device support as described in the relevant device standard, for example, Sheffield mannequin head with attachments or mannequin body with attachments.
Calibrated within the appropriate range and the accuracy of the breathing resistance limit specified in the relevant device standard pressure gauge which is better than 10% of its value.

Test Procedure:
The respirator is adjusted in accordance with its shape to deliver the respiratory volume in the minute specified in the relevant device standard.
One mouth of the pressure meter is connected to the pressure mouth of the support of the device and the other mouth to the environment. The pressure gauge is connected to the recorder device.
The device is leakproofly mounted on the support without any deformity. For headers that seal the neck circumference, the relevant fitting should be used. The "zero" reading of the pressure gauge is noted. The breathing machine switch is opened and the device is operated as described in the relevant device standard and the peak pressure is recorded.

Testing Laboratory: 1309 Coffeen Avenue STE 1200, Sheridan, WY, 82801, USA
Tel.:307-207-4535 Fax: 307-207-4535 E-mail: mdd@nptesting.com www.nptesting.com

Test results:
The test results obtained are given in the tables as follows

Inhalation Resistance

No. of Sample	Condition	Inhalation Resistance (mbar)				
		Flow rate 30 l/min	Requirements in accordance with EN 149:2001+A1:2009	Flow rate 95 l/min	Requirements in accordance with EN 149:2001+A1:2009	Assessment of Test Result Conformity / Nonconformity
29	As received	0,5	FFP1 ≤ 0,60 FFP2 ≤ 0,70 FFP3 ≤ 1,0	1,5	FFP1 ≤ 2,10 FFP2 ≤ 2,40 FFP3 ≤ 3,00	Passed
30		0,4		1,3		Passed
31		0,5		1,6		Passed
1	Simulated wearing treatment	0,5		1,4		Passed
2		0,6		1,5		Passed
3		0,6		1,4		Passed
13	Temperature conditioned	0,5		1,6		Passed
14		0,5		1,7		Passed
15		0,5		1,7		Passed

Exhalation Resistance

No. of Sample	Condition	Flow rate	Facing directly	Facing vertically upwards	Facing vertically downwards	Lying on the left side	Lying on the right side	Requirements in accordance with EN 149:2001+A1:2009	Assessment of Test Result Conformity / Nonconformity
29	As received	160l/min	2,2	2,1	2,1	2,3	2,0	FFP1 ≤ 3,0 FFP2 ≤ 3,0 FFP3 ≤ 3,0	Passed
30			2,0	2,0	2,1	2,0	2,4		Passed
31			2,2	2,1	1,9	2,1	2,0		Passed
1	Simulated wearing treatment		2,2	2,2	2,0	2,3	2,4		Passed
2			2,0	2,3	2,0	2,0	2,2		Passed
3			2,1	2,3	2,0	2,1	2,1		Passed
13	Temperature conditioned		2,0	2,4	2,4	2,2	2,3		Passed
14			2,1	2,2	2,1	2,2	2,1		Passed
15			2,0	2,1	1,9	2,0	2,0		Passed

Testing Laboratory: 1309 Coffeen Avenue STE 1200, Sheridan, WY, 82801, USA
Tel.:307-207-4535 Fax: 307-207-4535 E-mail: mdd@nptesting.com www.nptesting.com

Shenzhen WST Testing Co., Ltd.
No. 85, Guangshen Road, Xin 'an Street, Bao 'an District,
Shenzhen, Guangdong
Phone: +86 0755-27822875 Fax: +86 4008266163-02996

TEST REPORT

Particulate respirator-half facepiece

EN 149: 2001 +A1: 2009 Respiratory protective devices — Filtering half masks to protect against particles — Requirements, testing, marking

Product:	**ANTIPARTICLE MASK**
Report No:	**2020 (F) - 0142**
Order No.:	**32006334**
Client:	**Guangdong Yidao Medical Technology Co., Ltd** **Novaelectronica Iberia SL & Qualimax International SL**
Model (s):	**YD-002**
Date(s) of tests:	**2020.06.22-2020.06.23**

DESCRIPTION OF SAMPLES

General Information	**Classification**	**Main Components**
	FFP2 NR	White folding mask
Manufacturer	Guangdong Yidao Medical Technology Co., Ltd	
Manufacturer Address	Room 302, Building 2, No.1, Lane 1, Xiju Road, Hengli, Dongguan Dongguan City, Guangdong Province, P.R. China	

Signed: 

Issued: 2020.6.23

Conditions:

The test results presented in this report relate to the samples tested only.

This report may be reproduced and distributed to your clients, provided that it is reproduced and distributed in full.

The authenticity of this test report and its contents can be verified by contacting the laboratory.

Test Results

7.1 Package **Pass[1]**

Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.

Note2: In accordance with the requirement.

7.2 Material **Pass[2]**

Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used.

Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.

After undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps.

When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse.

Note3: No mechanical failure after undergoing the conditioning described in 8.3.1. No collapse when conditioned in accordance with 8.3.1 and 8.3.2.

7.3 Practical performance **Pass[3]**

The particle filtering half mask shall undergo practical performance tests under realistic conditions.

Note5: No imperfections.

7.4 Finish of parts **Pass[4]**

Parts of the device likely to come into contact with the wearer shall have no sharp edges or burrs.

Note6: No sharp edges or burrs.

7.5 Penetration of filter material **Pass[5]**

The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1.

	Sodium chloride test 95 l/min	Paraffin oil test 95 l/min
FFP1	≤20%	≤20%

Report No: 2020 (F) - 0142

FFP2	≤6%	≤6%
FFP3	≤1%	≤1%

Note8: FFP2 respirator. Test results are shown in Annex A Table 7.9.2.

7.6 Flammability **Pass[6]**

When tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5 s after removal from the flame.

7.7 Field of vision **Pass[7]**

The field of vision is acceptable if determined so in practical performance tests.

Note13: Pass the practical performance tests.

7.8 Breathing resistance **Pass[8]**

Classification	Maximum permitted resistance (mbar)		
	Inhalation		Exhalation
	30 l/min	95 l/min	160 l/min
FFP1	0.6	2.1	3.0
FFP2	0.7	2.4	3.0
FFP3	1.0	3.0	3.0

Note15: FFP2 respirator. Test results are shown in Annex A Table 7.16.

7.9 Demountable parts **Pass[9]**

All demountable parts (if fitted) shall be readily connected and secured, where possible by hand

Note17: In accordance with the requirement.

End of Test Results

Table -7.5 Filter Efficiency of filter material

Test specification: EN 149-2001 Clause 8.11

Aerosol	Condition	Sample No.	Filter Efficiency (%)	Assessment
Sodium chloride test	As received			Pass
	Simulated wearing treatment			
	Mechanical strength+ Temperature conditioned			
Paraffin oil test	As received	1	97.913	
		2	98.216	
		3	98.458	
	Simulated wearing treatment	4	98.909	
		5	97.899	
		6	97.514	
	Mechanical strength+ Temperature conditioned	7	98.300	
		8	96.575	
		9	95.973	
Flow conditioning： Single filter: 95.0 L/min				

Table 7.8 Breathing resistance (mbar)

Test specification: EN 149-2001 Clause 8.9

As received	Flow rate		1					2					3				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
	Inhalation	30 l/min	0.4					0.3					0.4				.
		95 l/min	1.9					1.5					2.0				.
	Exhalation	160 l/min	2.5					2.1					2.45				
Simulated wearing treatment	Flow rate		4					5					6				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
	Inhalation	30 l/min	0.4					0.4					0.3				.
		95 l/min	1.8					1.8					1.4				.
	Exhalation	160 l/min	2.6					2.6					2.2				
Temperature conditioned	Flow rate		7					8					9				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
	Inhalation	30 l/min	0.4					0.3					0.4				.
		95 l/min	2.0					1.7					1.5				.
	Exhalation	160 l/min	2.5					2.2					2.5				
Assessment	Pass																

A: facing directly ahead; B: facing vertically upwards; C: facing vertically downwards; D: lying on the left side; E: lying on the right side

End of Annex A

ANNEX B PHOTOS OF SAMPLES

End of Annex B