MASCARILLA QUIRURG TI 3/C 50UD

30/05/2020 V1.0

Código 018188

Descriptiva

Mascarilla de un solo uso.
Compuesta de tres capas con una filtración superior del 95%.
De material no tejido.

Specifications of Single-use Face Mask

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1 Introduction

The mask consists of three layers of non-woven fabric. The outer layer is blue polypropylene spunbond non-woven fabric, the middle layer is polypropylene meltblown non-woven fabric with bacteria and particle filtering effect, and the inner layer is white polypropylene spunbond non-woven fabric. The masks are suitable for wearing in an ordinary medical environment, blocking the exhalation or spraying of pollutants from the oral or nasal cavities. Used in non-invasive operation, bacterial filtration efficiency is over 95%.

2 Standard

The mask products are based on standards: EN 14683: 2005 Type Ⅰ (CE)

3 Product appearance

Fig.1 product appearance

Fig.2 product appearance

4 Specification

4.1 Size and appearance requirements

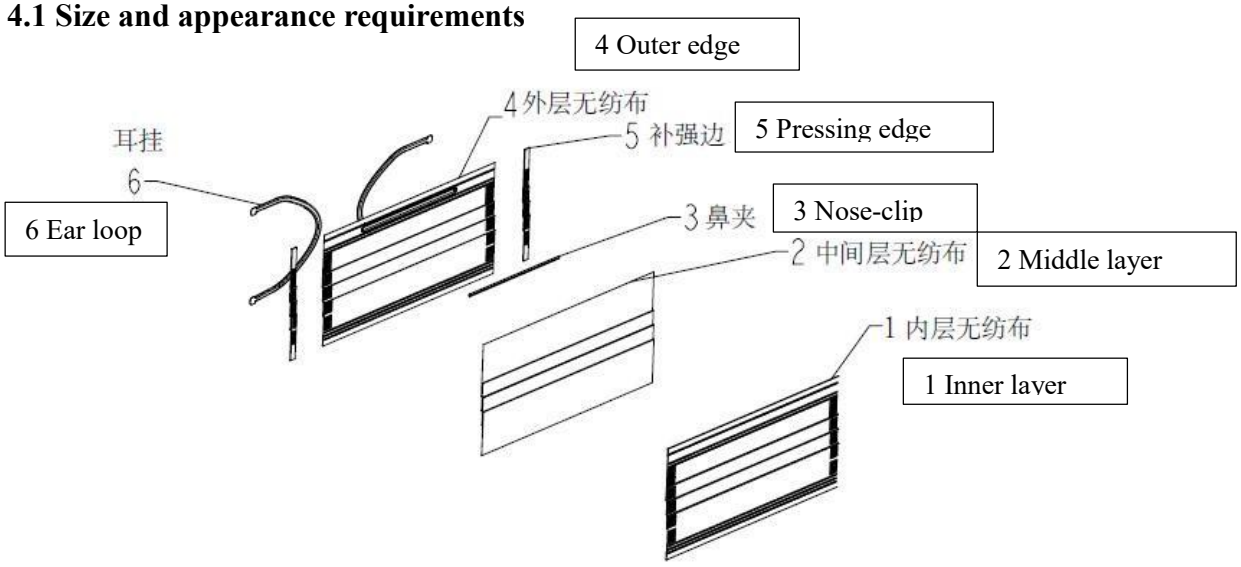


Fig.3 mask structure

1. Mask length >170 mm

2. Mask width: 165 mm, three stacks in the middle, the width of the mask after stacked is 95 mm, and the width of each stack ≥10 mm. The nose-clip side as the upper part and the dark colour as the outer side. After opening the stack, the opening side should face down

3. The width of the pressing edge ≤ 10 mm, and the upper nose-clip ≤ 16 mm

4. Nose-clip: Length>80 mm width is preferably 3mm

5. Ear-loop: The length is 180 mm and diameter is 3 mm. The material is polyester spandex. The inner layer is welded and the distance from the mask edge is not more than 10 mm.

Table 1 Parameters of single-use face masks

Items	Parameters
Product name	Single-use face mask
Textures	Polypropylene spunbond non-woven fabric, polypropylene melt-blown non-woven fabric, metal core plastic nose-clip.
Model	Flat
Size	175 mm * 95 mm
Application	Used mainly for respiratory protection of related personnel, which can filter particles in the air and block droplets and microorganisms.
Expiration date	The validity period is subject to the validity period promised by the non-woven fabric supplier, and the maximum period shall not exceed three years.
Packaging size	5 pcs / bag, 50 pcs / box, 2000 pcs / carton

Items	Parameters
Sterilization type	Non-sterile
Usage	1. Flatten the mask and hang both sides of the mask on your ears; 2. Fix the nose-clip in the shape of the nose to prevent ~~dirty~~ air from entering; 3. Pull the mask to the lower jaw so as to produce a good protective effect.
Special storage conditions and methods	Store in a relative humidity not exceeding 80%, non-corrosive gas, in a well-ventilated room and avoiding high temperatures.
Remarks	Epidemic emergency products

4.2 Inner and outer spunbond non-woven fabrics

The inner and outer layers are polypropylene spunbond non-woven fabrics. The outer layer is generally blue, the inner layer is white and the areal density is 25g / m². The width is based on the equipment width, the inner layer width is 200 mm, and the outer layer width is 180 mm. The packaging method is coil and the diameter of the coil cannot be greater than the equipment mounting limit. It requires sealed packaging.

The technical requirements for the inner and outer spunbond nonwovens are shown in Table 2:

Table 2 the technical requirements for the inner and outer spunbond nonwovens

Items		Index
Areal density		25 g/m^2
Breaking strength	Longitudinal	26 N/5cm
	Horizontal	18 N/5cm
Fluorescence		None
Formaldehyde content		≤ 300 mg/kg
pH		5.4-7.6
Microbial index	Total number of bacteria	cfu/g ≤20
	Coliform	None
	Pathogenic pyogenic bacteria	None
	Total fungal colonies	None
Biological evaluation	Cytotoxicity	Not more than 2 levels
	Skin irritation	Primary stimulation index does not exceed 0.4
	Delayed hypersensitivity	None

4.3 Interlayer meltblown non-woven fabric

The meltblown non-woven fabric is made of high-speed hot air to draw polypropylene (PP) to form ultra-fine fiber agglomeration. Its specifications are white and its areal

density is 25 g / m². The packaging method is coil, the diameter of the coil cannot be larger than the equipment mounting limit and the package is sealed.

The technical requirements for the interlayer meltblown non-woven fabric are shown in Table 3

Table 3 the technical requirements for the interlayer meltblown non-woven fabric

Items		Index
Areal density		25 g/m^2
Fluorescence		None
Formaldehyde content		≤ 300 mg/kg
pH		5.4-7.6
Microbial index	Total number of bacteria	cfu/g ≤20
	Coliform	None
	Pathogenic pyogenic bacteria	None
	Total fungal colonies	None
Particle filtration efficiency		≥ 30 %
Bacterial filtration efficiency		≥ 95 %

4.4 Left and right reinforcing edges

The left and right reinforcing edges are polypropylene spunbond non-woven fabrics, which are used to fix the ear-loop and three layers of non-woven fabrics together. 20 mm wide, white, areal density 35 g / m², packed in rolls, sealed.

4.5 Nose-clip

Nose-clip is made of PP plastic with galvanized iron wire core, length ≥ 80 mm, width 2.5 mm ~ 3 mm. It has plasticity and fits the nose shape by pressing down to increase the effective tightness of the mask.

4.6 Ear loop

The ear loop is generally made of polyester spandex which is connected to the mask body by ultrasonic welding. The ear-loop elasticity is designed to fit comfortably and to effectively fix the position of the mask in place. Generally, it is 180 mm. The package is sealed.

5 Product testing requirements

According to Article (8) of the ‘Guiding Principles for the Technical Review of Medical Mask Product Registration’：

Product testing requirements: The testing of medical mask products includes factory inspection and type inspection. The factory inspection items should have at least the following items: appearance, structure and size, nose-clips, mask bands,

microbiological indicators, and ethylene oxide residue (if ethylene oxide sterilization is used). The type inspection shall be the full performance inspection of the product standard. Specific testing items and requirements are shown in Table 4.

Table 4 Testing items and requirements for finished masks

S.N.	Test items	Requirements
1	Appearance	Type inspection, factory inspection
2	Structure and size	Type inspection, factory inspection
3	Nose-clip	Type inspection, factory inspection
4	Ear loop	Type inspection, factory inspection
5	Ventilation resistance	Type inspection
6	Bacterial filtration efficiency (BFE)	Type inspection
8	Sterilization requirements	E.O. sterilization, irradiation sterilization is prohibited, non-sterile products are not required
9	Skin irritation	Type inspection, supplier raw material inspection report
10	Cytotoxicity	Type inspection, supplier raw material inspection report
11	Delayed hypersensitivity	Type inspection, supplier raw material inspection report

6 Requirements for production environment and process hygiene

The production workshop should meet the requirements of '100,000 air cleanliness class'.

Requirements:

1. Maximum allowable number of dust particles: no more than 3.5 million particles ≥ 0.5 μm; no more than 20,000 particles ≥ 5 μm;
2. The maximum allowable number of microorganisms: the number of planktonic bacteria does not exceed 500 / m3; the number of sedimentary bacteria does not exceed 10 / culture dish;
3. Pressure difference: The pressure difference between clean rooms of the same cleanliness level is the same. The pressure difference between adjacent clean rooms of different cleanliness levels should be ≥ 5 Pa, and the clean room and non-clean rooms should be ≥ 10 Pa (mainly to ensure that air from the clean area flow to non-clean areas to avoid airflow backwashing);
4. Temperature and humidity. The temperature is generally controlled 20 ~ 22 ℃ in winter; 24 ~ 26℃ in summer; fluctuation ± 2 ℃. The humidity of clean room in winter is controlled at 30-50%, and the humidity of clean room which in summer

is controlled at 50-70%. When there are no special requirements for temperature and humidity, it is advisable to wear clean work clothes without discomfort.

7 Labeling and packaging requirements

According to regulatory requirements, product packaging should include the following information.

7.1 Labeling requirements

1. Product name, size and model type;

2. Production date / lot number, manufacture date or expiration date;

3. Manufacturer name, address and contact information;

4. Name, address, and contact information of the registrant or recorder;

5. Implementation of standard number, product registration certificate number, production license number / production filing certificate number;

6. The record number of the equipment urgently needed for the epidemic situation;

7. Instructions for use (at least including front and back identification and wearing methods);

8. Storage conditions, special storage, operating conditions or instructions;

9. 'Single use' words or symbols;

10. If it is a sterilised product, it should have a corresponding sterilisation mark, and indicate the sterilisation method used and the sterilisation period

11. Product Usage;

12. The 'emergency product' is marked clearly;

13. If the medical device can be marketed as sterile or non-sterile, the packaging or labelling of the product should be distinguished;

14. According to product characteristics, graphics, symbols and other related content should be marked;

15. Necessary warnings, precautions;

7.2 Specification requirements：

1. Product name, model, specifications;

2. Applicant / manufacturing company name, residence, production address, contact information and after-sales service unit;

3. Recording certificate number of urgently needed equipment for prevention and control;

4. Product performance, main structural composition or composition, scope of application;

5. Contraindications, precautions, warnings and tips;

6. Installation and use instructions or diagrams, medical devices used by consumers themselves should also have special instructions for safe use;

7. Product maintenance and maintenance methods, special storage and transportation conditions and methods;

8. Production date or expiration date;

9. List of spare parts, including parts, accessories, replacement cycle of consumables, and instructions for replacement methods;

10. Explanation of graphics, symbols, abbreviations, etc. used in medical device labels;

11. Date of preparation or revision of the manual;

12. The ‘emergency product’ must be marked prominently.

7.3 Packaging requirements

The PE bag should be sealed and packed in a carton. Use as soon as possible after the sealed bag is opened to prevent contamination.

BYD Single-use Face Mask User Instructions

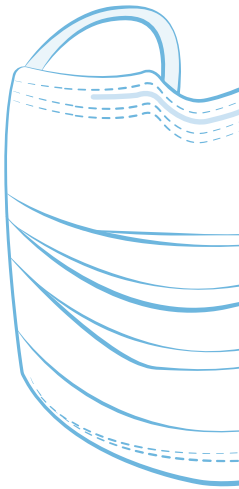
Notice d'utilisation du masque facial à usage unique BYD

BYD Istruzioni per l'uso della maschera facciale per uso singolo (monouso)

Gebrauchsanweisungen für Einweg-Atemschutzmasken von BYD

Gebruiksaanwijzing voor BYD gezichtsmaskers voor eenmalig gebruik

Instrucciones de uso de las mascarillas de un solo uso de BYD



LATEX

EN 14683:2005 Type I **Product Model: FLAT**

BYD Single-use face masks consist of three layers of nonwoven material

Le masque facial à usage unique BYD se compose de trois couches en non-tissé

BYD Le maschere facciali monouso sono costituite da tre strati di tessuto non tessuto

Einweg-Atemschutzmasken von BYD bestehen aus drei Vliesschichten

BYD-gezichtsmaskers voor eenmalig gebruik bestaan uit drie lagen, vervaardigd uit ongeweven materiaal

Las mascarillas de un solo uso de BYD se componen de tres capas de un material no tejido

Outer Layer
Blue polypropylene spunbond nonwoven

Couche extérieure
Non-tissé Spunbond en polypropylène bleu

Strato esterno
Spunbond in polipropilene blu non tessuto

Äußere Schicht
Blaues Polypropylen-Spinnvlies

Buitenlaag
Blauw polypropyleen spunbond ongeweven materiaal

Capa exterior
Poliéster de polipropileno no tejido azul

Inner Layer
White polypropylene spunbond nonwoven

Couche intérieure
Non-tissé Spunbond en polypropylène blanc

Strato interno
Spunbond in polipropilene bianco non tessuto

Innere Schicht
Weißes Polypropylen-Spinnvlies

Binnenlaag
Wit polypropyleen spunbond ongeweven materiaal

Capa interior
Poliéster de polipropileno no tejido blanco

Middle Layer
Polypropylene melt-blown nonwoven with pathogen filtering

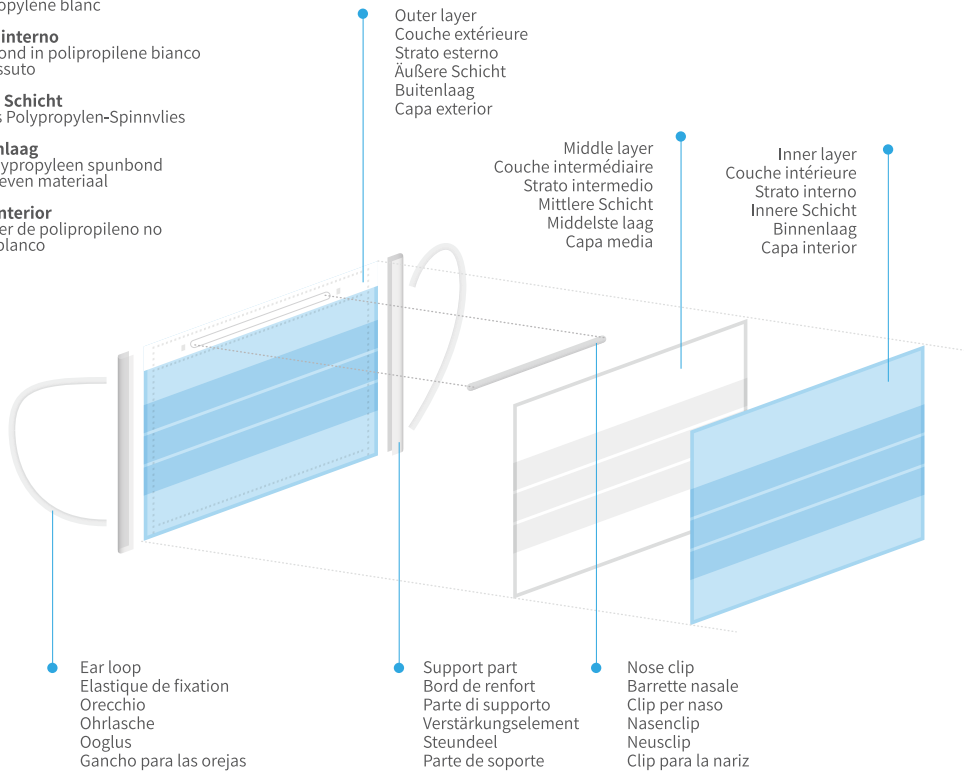
Couche intermédiaire
Non-tissé en polypropylène Meltblown avec filtrage des pathogènes

Strato intermedio
Tessuto non tessuto soffiato a fusione in polipropilene con filtro patogeno

Mittlere Schicht
Schmelzgeblasenes Polypropyl-en-Vlies, filtert Krankheitserreger heraus

Middelste laag
Polypropyleen melt-blown ongeweven met pathogeenfiltering

Capa media
Fibra de polipropileno no tejido y fundida con filtrado de patógenos



Product Specifications

1 Mask length: > 170 mm.
2 Mask expansion width: 165 mm. Post-stack width is 95 mm with three stacks in the middle. Each stack width is not less than 10 mm. The nose clip is located on the upper edge of the mask, and the outside of the mask is darker in color.
3 The width of the support part is not more than 10 mm, and the position of the upper nose clip is not more than 16 mm.
4 Metal core plastic nose-clip: length > 80 mm; width approximately 3 mm.
5 Ear loop: 180 mm in length and 3 mm in diameter, composed of polyester, spandex and other materials.

Parameter

Product name	Single-use Face Mask
Bacterial filtration efficiency	⩾ 95 %
Model	Flat
Size	175mm x 95mm
Weight	3.2 g
Expiration date	2 years after production
Packaging specification	10 pcs/bag; 50 pcs/box; 2000 pcs/carton
Packaging dimensions (L x W x H)	Carton: 520 x 400 x 470mm Box: 190x100x110mm Bag: 220 x 108mm
Sterilization	Non-sterile

Important limitations

1 Please use the product within the period of validity.
2 One-time use only. Disposal of contaminated products should be considered as hazardous waste and in accordance with national regulations.
3 Duration of use: 4 hours.
4 Do not use if packaging is damaged.
5 Indesirable effects and incidations: in contact with the skin, the mask can cause allergic reactions on sensitive people. If this is the case, remove the mask and seek medical advice.
6 Please read the instructions carefully before using.

Storage

Store in a well-ventilated place with relative humidity below 80%; avoid high temperatures, corrosive gas and exposure to flame.

Warning

This mask does not eliminate the risk of contracting any disease or infection.
Change immediately if contaminated with blood or body fluid.

Spécifications du produit

1 Longueur du masque: >170 mm.
2 Largeur du masque ouvert: 165 mm. La largeur fermée est de 95 mm avec trois plis au milieu. Chaque pli doit être supérieur ou égal à 10 mm. La barrette nasale doit être positionnée vers le haut, la partie bleue vers l'extérieur.
3 La largeur du bord de renfort ne doit pas dépasser 10 mm et la barrette nasale supérieure ne doit pas dépasser 16 mm.
4 Barrette nasale en métal recouvert de plastique : Longueur >80 mm, largeur: 3 mm.
5 Elastique de fixation: La longueur est de 180 mm, le diamètre est de 3 mm. Composé de polyester, spandex et autres matériaux.

Fiche technique

Nom du produit	Masque facial à usage unique
Efficacité de filtration bactérienne	⩾ 95 %
Modèle	Plat
Dimensions	175mm x 95mm
Poids	3,2 g
Date d'expiration	2 ans après la date de production
Conditionnement	10 pièces / sachet, 50 pièces / boîte, 2000 pièces / carton
Dimensions des emballages (L x l x H)	Carton: 520 x 400 x 470mm Boîte: 190x100x110mm Sachet: 220 x 108mm
Stérilisation	Non stérile

Restrictions importantes

1 Veuillez utiliser le produit pendant la période de validité.
2 Uniquement à usage unique, veuillez jeter le produit après usage conformément à la réglementation en vigueur.
3 Durée d'utilisation: 4 heures.
4 Ne pas utiliser si l'emballage est endommagé.
5 Les personnes allergiques aux non-tissés doivent l'utiliser avec précaution.
6 Veuillez lire attentivement les instructions avant utilisation.

Stockage

Stocker dans une pièce dont le taux d'humidité relative ne dépasse pas 80%, sans gaz corrosif et bien ventilée, et à l'abri des températures élevées.

Avertissement

Ce masque n'élimine pas le risque de contracter une maladie ou une infection.
A changer immédiatement en cas de contamination par du sang ou des liquides organiques.

Specifiche del prodotto

1 Lunghezza della maschera:> 170 mm.
2 Larghezza di espansione della maschera: 165 mm. La larghezza della pila e la successiva è di 95 mm con tre pile al centro. Ogni pila misura almeno10 mm. La clip per il naso si trova sul bordo superiore del maschera e la parte esterna della maschera è di colore più scuro.
3 La larghezza della parte di supporto misura al massimo 10 mm e la posizione della clip nasale superiore misura al massimo 16 mm.
4 Clip per il naso in plastica con nucleo metallico: lunghezza> 80 mm; larghezza circa 3 mm.
5 Elastico per l'orecchio: 180 mm di lunghezza e 3 mm di diametro, composto da poliestere, spandex e altri materiali.

Parametri

Nome del prodotto	Mascherina facciale uso singolo
Efficacia di filtrazione batterica	⩾ 95 %
Modello	Piatto
Dimensioni	175mm x 95mm
Peso	3,2 g
Data di scadenza	2 anni dopo la data di produzione
Specifiche del pacco	10 pezzi/confezione; 50 pezzi/scatola; 2000 pezzi/sacco
Dimensioni del pacco (L x W x H)	Confezione: 520 x 400 x 470mm Scatola: 190x100x110mm Sacco: 220 x 108mm
Sterilizzazione	Non-sterile

Limitazioni importanti

1 Si prega di utilizzare il prodotto entro il periodo di validità.
2 Solo per uso singolo lo smaltimento di prodotti contaminati deve essere considerato come rifiuto pericoloso e in conformità con le normative nazionali.
3 Durata dell'uso: 4 ore.
4 Non utilizzare se l'imballaggio è danneggiato.
5 Effetti ed incidenti indesiderati: a contatto con la pelle, la maschera può causare reazioni allergiche a persone sensibili, in tal caso, rimuovere la maschera e consultare un medico.
6 Leggere attentamente le istruzioni prima dell'uso.

Conservazione

Conservare in luogo ben ventilato con umidità relativa inferiore all'80%; evitare temperature elevate, gas corrosivi ed esposizione alle fiamme.

Avvertenze

La maschera non elimina il rischio di contrarre qualsiasi malattia o infezione.
Sostituire immediatamente se contaminata con del sangue o dei fluidi corporei.

Technische Daten des Produkts

1 Maskenlänge: > 170 mm.
2 Maskenbreite, ausgefaltet: 165 mm. Gefaltet beträgt die Breite 95 mm mit drei Falten in der Mitte. Die einzelnen Falten weisen eine Breite von min. 10 mm auf. Der Nasenclip befindet sich am oberen Rand der Maske und die Außenseite der Maske hat eine dunklere Farbgebung.
3 Die Breite des Verstärkungselements beträgt max. 10 mm und die Position des oberen Nasenclips beträgt max. 16 mm.
4 Kunststoff-Nasenclip mit Metallkern: Länge > 80 mm; Breite ca. 3 mm.
5 Ohrlasche: Länge 180 mm und Durchmesser 3 mm, besteht aus Polyester, Elastan und weiteren Materialien.

Parameter

Produktbezeichnung	Einweg-Atemschutzmaske
Bakterielle Filtereffizienz	⩾ 95 %
Modell	Flach
Größe	175mm x 95mm
Gewicht	3,2 g
Haltbar bis	2 Jahre nach Produktion
Verpackungsangaben	10 Stck./Beutel; 50 Stck./Schachtel; 2000 Stck./Karton
Verpassungsabmessungen (L x B x H)	Karton: 520 x 400 x 470mm Schachtel: 190x100x110mm Beutel: 220 x 108 mm
Sterilisierung	Nicht steril

Wichtige Einschränkungen

1 Das Produkt nur innerhalb des Haltbarkeitszeitraums verwenden.
2 Nur einmalig verwenden. Bei der Entsorgung ist das Produkt als Sondermüll gemäß den entsprechenden Regelungen für das jeweilige Land zu behandeln.
3 Verwendungsdauer: 4 Stunden.
4 Nicht verwenden, wenn die Verpackung beschädigt ist.
5 Unerwünschte Nebenwirkungen und Reaktionen: Bei Personen mit empfindlicher Haut kann die Maske zu allergischen Reaktionen führen. In diesem Fall die Maske ablegen und einen Arzt hinzuziehen.
6 Vor dem Gebrauch die Gebrauchsanweisungen sorgfältig lesen.

Lagerung

An einem belüfteten Ort mit relativer Luftfeuchtigkeit unter 80% lagern; vor hohen Temperaturen, Schadgas und offenem Feuer schützen.

Warnung

Diese Maske ist kein absoluter Schutz vor Krankheiten oder der Infektion durch Krankheitserreger.
Das Produkt bei Verunreinigung mit Blut oder Körperflüssigkeiten sofort wechseln.

Productspecificaties

1 Maskerlengte: > 170 mm.
2 Masker uitrekbare breedte: 165 mm. De breedte na stapeling bedraagt 95 mm met drie stapels in het midden. Iedere stapelbreedte is niet minder dan 10 mm. De neusclip bevindt zich op de bovenste rand van het masker en de buitenzijde van het masker heeft een donkerdere kleur.
3 De breedte van het steundeel is niet meer dan 10 mm, en de positie van de bovenste neusclip is niet meer dan 16 mm.
4 Plastic neusclip met metalen kern: lengte > 80 mm; breedte ca. 3 mm.
5 Oorlus: 180 mm in lengte en 3 mm in diameter, vervaardigd van polyester, spandex en andere materialen.

Parameter

Productnaam	Gezichtsmaskers voor eenmalig gebruik
Bacteriële filtratie-effectiviteit	⩾ 95 %
Model	Plat
Maat	175 mm x 95 mm
Gewicht	3,2 g
Houdbaar tot	2 jaar na productie
Verpakkingsspecificatie	10 stuks/zak; 50 stuks/verpakking; 2000 stuks/doos
Verpakkingsafmetingen (L x B x H)	Doos: 520 x 400 x 470mm Verpakking: 190x100x110mm Zak: 220 x 108mm
Sterilisatie	Niet steriel

Belangrijke beperkingen

1 Gebruik het product binnen de houdbaarheidstermijn.
2 Alleen geschikt voor eenmalig gebruik. Vervuilde producten moet worden behandeld als gevaarlijke stoffen afval en de afvoer daarvan moet plaatsvinden overeenkomstig de nationale regelgeving.
3 Gebruiksduur: 4 uur.
4 Niet gebruiken als de verpakking beschadigd is.
5 Ongewenste effecten en indicaties: bij huidcontact kan het masker allergische reacties veroorzaken bij gevoelige mensen. Als dit het geval is, moet u het masker verwijderen en medisch advies inwinnen.
6 Instructies zorgvuldig lezen voor het gebruik.

Opslag

Opslaan op een goed geventileerde plaats met een relatieve vochtigheidsgraad van minder dan 80%; blootstelling aan corrosief gas en vuur vermijden.

Waarschuwing

Dit masker kan het risico van besmetting door ziekte of infectie niet verhinderen.
Het masker onmiddellijk vervangen als het met bloed of lichaamsvloeistoffen vervuild is geraakt.

Especificaciones del producto

1 Longitud de la mascarilla: > 170 mm.
2 Ancho de expansión de la mascarilla: 165 mm. Ancho después de plegago es de 95 mm con tres pliegues en el medio. El ancho de pliegue no es inferior a 10 mm. El clip de la nariz está ubicado en el borde superior de la mascarilla y la parte exterior de la mascarilla es de un color más oscuro.
3 El ancho de está parte de soporte no es superior a 10 mm y la posición del pasador superior no es superior a 16 mm.
4 Clip para la nariz de plástico con núcleo metálico: Longitud > 80 mm; ancho aprox. 3 mm.
5 Gancho para la oreja: 180 mm de longitud y 3 mm en diámetro, compuerto de poliéster, licra de poliéster y otros materiales.

Parámetro

Nombre del producto	Mascarilla de un solo uso
Eficacia del filtrado bacteriano	⩾ 95 %
Modelo	Liso
Tamaño	175 mm x 95 mm
Peso	3,2 g
Fecha de caducidad	2 años después de la producción
Especificación de embalaje	10 piezas/bolsa; 50 piezas/bolsa; 2000 piezas/bolsa
Dimensiones del embalaje (L x An x Al)	Cartón: 520 x 400 x 470mm Caja: 190x100x110mm Bolsa: 220 x 108 mm
Estelización	No estéril

Limitaciones importantes

1 Use el producto dentro de su periodo de validez.
2 Solo de un solo uso. Desecho de los productos contaminado se considerará como desechos peligrosos y deben desecharse según las regulaciones nacionales.
3 Duración de uso: 4 horas.
4 No la use si el paquete está dañado.
5 Efectos e indicaciones indeseables: en contacto con la piel, la mascarilla puede causar reaccionanes en personas sensibles. Si este es el caso, quítese la mascarilla y pida consejo a un médico.
6 Lea las instrucciones con atención antes de usarlas.

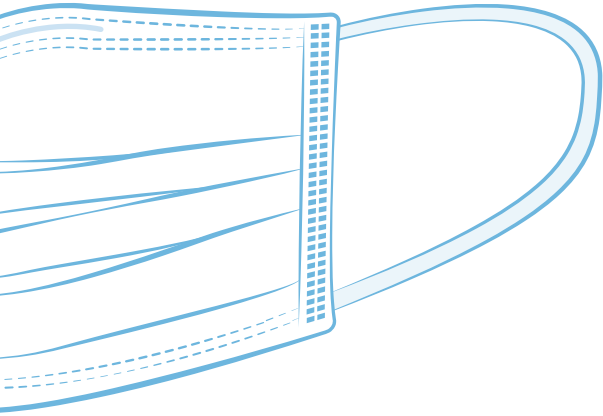
Almacenamiento

Guarde un lugar bien ventilado con la humedad relativa inferior a 80 %, evite altas temperaturas, gas corrosivo y exposición a llamas.

Advertencia

La mascarilla no elimina el riesgo de contraer enfermedades o infecciones.
Cámbiela inmediatamente si se ha manchado de grasa o líquidos corporales.

BYD CARE



BYD Precision Manufacture Co., Ltd.
No. 3001 Baohe Road, Baolong Industrial City,
Longgang, Shenzhen, China

EC REP

Wellkang Ltd
16 Castle St,Dover, Kent, CT16 1PW,England,UK

Tel: +86 755-89888888

Test Report

Report No.: GZES200401421704

Date: 2020-04-24

The following sample(s) was/were submitted and identified on behalf of the applicant as:

Applicant:	BYD Precision Manufacture Co., Ltd.
	NO.3001 Baohe Road, Baolong Industrial Area, Longgang,Shenzhen
Manufacturer:	The same as the applicant
Sample Name:	Single-use face mask
Lot No. :	/
Quantity:	50 PCS
Model/Type Reference:	Flat/17.5×9.5cm
Date of Sample Received:	2020-03-19
Date of Testing:	2020-03-19 to 2020-04-06
The Standards:	EN 14683:2019
Test Items:	Bacterial filtration efficiency (BFE), Differential pressure and Microbial cleanliness as required by applicant
Test Result:	-Please refer to next page(s)-
Remark:	The test was carried out by external laboratory which assessed as competent.

Jova Lan

Jova Lan
Technical Manager
Medical Laboratory
SGS-CSTC Standards Technical Services Co., Ltd. Guangzhou Branch

Table 1

Test Items		Result - Remarks	Test Methods
Differential Pressure (Pa/cm^2)	1	24.8	EN 14683:2019 Annex C
	2	24.4	
	3	26.5	
	4	25.2	
	5	26.0	

Table 2

Test Items		Result - Remarks	Test Methods
Bacterial Filtration Efficiency (BFE)(%) Staphylococcus aureus ATCC 6538	1	99.1	EN 14683:2019 Annex B
	2	99.5	
	3	99.5	
	4	99.2	
	5	99.1	

Note: Control average: 2196 CFU.
Note: Mean particle size: 2.8 μm.
Note: Testing side: outside of specimen.
Note: Testing area: 39.5 cm^2.

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Table 3

Test Items		Result - Remarks	Test Methods
Microbial Cleanliness (cfu/g)	1	8.2	EN 14683:2019 EN ISO 11737-1:2018
	2	18.2	
	3	24.0	
	4	4.6	
	5	13.8	

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Photo documentation:

Sample description
Single-use face mask

-- End of this report--

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EC Declaration of Conformity

according to the Medical Devices Directive 93/42/EEC

***Class I** Medical Device*

(non-sterile, without measuring function)

Manufacturer:	BYD Precision Manufacture Co., Ltd
Address:	No. 3001 Baohe Road, Baolong Industrial City, Longgang, Shenzhen, China .
Tel:	Tel: 0755-89888888
Fax	Fax:
EC Rep:	Wellkang Ltd 16 Castle Street, Dover, CT16 1PW, England, UK

We,the manufacturer, declare under our sole responsibility that

the medical device(s)	Product Name	Single-use face mask
	Type/model, identification of product allowing traceability (Where applicable)	Flat/17.5cm×9.5cm
of class	according to annex IX of directive 93/42/EEC :	**Class I** Medical Device (non-sterile, without measuring function)

is/are in conformity with the relevant provisions and requirements of directive 93/42/EEC, as amended by Directive 2007/47/EC.

Applied harmonised standards, national standards or other normative documents	EN 14683:2005 EN ISO 15223-1:2016 EN 1041:2008 EN ISO 14971:2012 EN ISO 10993-1:2009 EN ISO 10993-5:2009
Conformity assessment procedure	**Module A (EC Declaration of Conformity (Annex VII) + Technical Files)**
Notified Body (name & number) Certificate & number	**NOT applicable**

Signed on: 9 March 2020. Place: Shenzhen, Guangdong, China

Signature (on behalf of the manufacturer) : 刘晓亮 Liu Xiao Liang

Name of authorized signatory: 刘晓亮 Liu Xiao Liang

Position held in the company: General Manager

Official Seal: