



3 PLY MEDICAL SURGICAL MASK

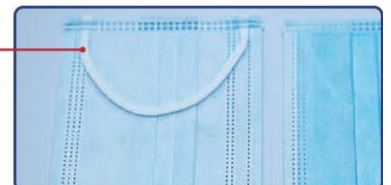
**CE / FDA
APPROVED**



Isolation and protection through filtration



The ear-loops medical surgical mask is more convenient to wear and remove



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C.F./P.IVA/N. Iscrizione Reg Imprese 02477680181 - REA: PV 276810
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Maschera chirurgica per la protezione da particelle (3PLY)

Description:

CE&FDA Certificated

Laboratory Tested and compliant with CE Certification and ISO
Consists of mask, nose-clip and tie-bands, made of non-woven fiber fabric
Isolation and protection through filtration
Particle filtration and bacterial filtration meet relevant standards.

Intended usage

These face masks, designed for medical personnel to wear over the face, prevent dandruff and respiratory microbes from spreading to open surgical wounds and stop the body fluids of patients from spreading to medical personnel thus to play a two-way biological protection role.

Structure and components

The Medical Surgical Mask is composed of ear loops, nose clip and tie-band, made of non-woven fiber fabric. Plays the role of isolation and protection through filtration, the fixed nose clip enhances the protection of the mouth and nose. The ear-loops medical surgical mask is more convenient to wear and remove.





Features

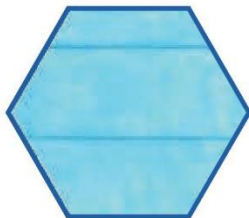
- * Tie-bands with sufficient strength to fix the mask. The breaking strength of the connection point between each tie-band and the mask is not less than 10N
- * The **PFE** (Particle Filtration Efficiency) is no less than **30%** and the **BFE** (Bacterial Filtration Efficiency) is no less than **95%**
- * Pressure difference between the two sides of the mask for air exchange $\Delta P \leq 49\text{Pa}$
- * Synthetic blood was sprayed on the mask sample at a pressure of 120mmHg and there was no penetration through the mask
- * Ethylene oxide residual does not exceed 10ug/g

Applicable users

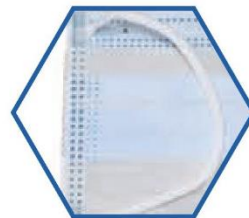
Medical staff in medical environment

Application method

1. Take the mask out and the nose-clip should be positioned at the top
2. Fully unfold the pleats of the mas
3. Place the mask on the face and make sure to cover the nose and face, fix the mask with the tie-bands or ear loops, for the nose -clip over the bridge of the nose and press the nose-clip with the middle fingers of both hands
4. Pull the mask from the top to bottom to cover the end of jaw to cover face and the protection
5. Check adhesion after putting on the mask: cover the mask with both hands, breath out. If there is leakage air from the nose-clip. Adjust the nose clip. If the adhesion cannot be achieved, do not wear the mask into the dangerous area



Two-way biological protection, prevent scurf, respiratory microorganisms from spreading to open surgical wounds ;



The ear-loops medical surgical mask is more convenient to wear and remove

Contraindications

1. Prohibition of modification and misuse of this product
2. This product does not produce oxygen and cannot be used in hypoxic environments
3. Do not use this product when facial beard, hair or other conditions affect the adhesion between the face and the mask
4. This product is a single-use product and re-use is prohibited



Precautions

1. Keep away from fire
2. Masks marked “sterilized” or “sterile” on the package or with a sterilization icon should be sterile. Before use, check the package for damage. Damaged products cannot be used. The sterilization method is ethylene oxide sterilization
3. Cannot be used in special environments such as harmful dust and gas
4. Ear loops might break if to be pulled with extra force
5. Please stop the usage of the mask, if there is itchiness and ear pain
6. If you have an injury to your mouth, nose or ear, please treat the wound before using it

【Medical surgical face masks specifications】

| Type | Length (±1cm) | Width(±1cm) |
|----------------|---------------|-------------|
| BH-EG-12×7 | 12 | 7 |
| BH-EG-14.5×9 | 14.5 | 9 |
| BH-EG-17.5×9.5 | 17.5 | 9.5 |
| BH-BD-12×7 | 12 | 7 |
| BH-BD-14.5×9 | 14.5 | 9 |
| BH-BD-17.5×9.5 | 17.5 | 9.5 |

Storage and transportation

Store and transport this product in a dry place at room temperature. Keep away from heat source. Pay attention to waterproof, high temperature, humidity and corrosion resistant gas. Keep out of direct sunlight and store in a clean, dry and well ventilated environment.

Validity

Two years



No secondary use

STERILE EO

Ethylene oxide
sterilization



No secondary
sterilization



Do not use if packaging
is damaged



Declaration of Conformity

Manufacturer Address ~~BEIJING BIOSIC HEALING BIOLOGICAL TECHNOLOGY CO., LTD~~
~~No. 6 plant west, Valley No. 1, Bio-medicine Industry Park, Daxing District,~~
102600 Beijing, PEOPLE'S REPUBLIC OF CHINA.

European Representative ~~SHANGHAI INTERNATIONAL HOLDING GROUP~~ GMBH (EUROPE)
~~EIFELSTRASSE 06, 20557~~ HAMBURG, GERMANY

We, the manufacturer, herewith declare that the products

Medical Surgical Mask

~~SH-EGP~~ (12×7,14.5×9,17.5×9.5)
~~SH-DDP~~ (12×7,14.5×9,17.5×9.5)

meet the provisions of Directive 93/42/EEC and 2007/47/EC which apply to them.
The medical device has been assigned to class I according to Annex IX of the
Directive 93/42/EEC. It bears the mark



WE, AS THE MANUFACTURER,
ARE EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY

Valid from: 2020 - 03 - 03
Valid until: 2024 - 05 - 27

Standard NO. EN 14683-2014 Type IIR

Signature of General Director