

Instruction For Use

Face Mask (Non-Sterile)

Artnr 40471200/2058434

**Product name:**

Face Mask (Non-Sterile)

Model and specification:

Flat Type/ 17.5cm x 9.5cm.

Intended use:

Face mask (non-sterile) is used for patients in order to reduce the risk of the spread of infections, and it is not intended for use by healthcare professionals in an operating room or in other medical settings with similar requirements. The product is disposable and non-sterile.

Product composition and material:

The product is composed of mask body, nose clip and mask ribbon. The mask body is composed of surface layer, filter layer and inner layer. The surface layer and the inner layer are made of non-woven fabric, and the filter layer is made of melt-blown non-woven fabric. The nose clip is made of malleable material, mask ribbon is made of elastic material or non-woven fabric.

Contraindication:

People allergic to non-woven fabrics are not allowed to use the product.

Caution and warning:

1. Check whether the package is in good condition before use, confirm the package identification, production date and validity period and use them within the validity period.
2. This product is disposable and should be disposed as medical waste after use.
3. The nose clip on the mask should not be flat frequently to prolong the use time.
4. Please keep in the shade and out of the reach of children.
5. It is not recommended to wear this product when the air is not circulating, breathing is not smooth or sleeping.
6. Children under three years old are not recommended because of their low vital capacity.
7. This product should not be used in a sterile surgical operation environment.
8. If any serious incident that has occurred in relation to the device. Please report to the manufacturer and the competent authority of your area.

The performance characteristics of the device:

1. Bacterial filtration efficiency (BEF), (%) $\geq 95\%$.
2. Differential pressure (Pa/cm²) < 40 Pa/cm².
3. Microbial cleanliness (cfu/g) ≤ 30 cfu/g.
(Meet EN14683:2019, Type I)

Method:

1. Unfold the fold of the mask to make it fully extended;
2. Pinch the nose clip along the bridge of the nose until it fits;
3. Wrap the mask around the face and put on the ear hook at the same time;
4. Pull the lower edge of the mask to the lower jaw to ensure a large area of protection effect;
5. After wearing each time, the air tightness inspection must be carried out: cover the mask with both hands and exhale. If there is gas leaking from the nose clip, it is necessary to readjust the nose clip.

Storage and transportation:

- Keep away from sunlight
- Keep dry
- Room temperature storage.

Product shelf-life:

2 years. See sales package for the production date and expiration date of the product.

Applicable technical standards:

EN 14683:2019+AC Face masks - Requirements and test methods

Manufacturer:

Company name: Crown Name Disposable Hygiene Products Fty., Ltd
Address: Chengbei Industrial Zone, Xinzhou District, Wuhan, China

European union authorization representative:

Company name: Lotus NL B.V.
Address: Koningin Julianaplein 10,1 e Verd,2595AA,The Hague, Netherlands.
Tel: +31644168999 Email: peter@lotusnl.com

Label identification:



LOT Batch code Q Please don't reuse it



Please read the instructions for use carefully before using



Non-sterile



Date of manufacture



The product meets the basic requirements of European in REGULATION (EU) 2017/745



Please don't reuse it



Medical Device



Keep dry



Protect from heat



Use by date



Food safe