

DATA SHEET



MASKITA®

Disposable surgical mask for adults

Item code: **MSK.P**

Type: **II R**

Risk class: **1**

Medical device class: **T020601**

DESCRIPTION

MASKITA® is a disposable surgical mask of type IIR for adults, non-sterile, produced in Italy.

It is CE marked and registered as medical device by the Ministry of Health, registration number: 2044413.

If properly worn it allows you to cover nose, mouth and chin helping to reduce the emission of water droplets containing viruses and bacteria, potentially present in the oral cavity and in the upper respiratory tract by the wearer.

Thanks to its proven resistance to splashes, it is also suitable for medical or health purposes.

COMPLIANCE

The medical device is comply with the following rules:

D. LGS. 46/1997, recepimento dir. 93/42/CEE

and with the followings technical regulations:

UNI EN 14683:2019

UNI EN 10993-1:2010

UNI EN 14971:2020

COMPOSITION AND TECHNICAL FEATURES

MASKITA® consists of 3 layers of white non-woven SMS fabric (Spunbond-Meltblown-Spunbond) made of polypropylene welded together through modern ultrasonic technologies. The spunbond composes the outer layers of the mask while the meltblown is contained in the central filtering layer. The mask is equipped with elastic bands for the correct and easy fastening behind the ears and a hake on the upper edge to allow a better adhesion to the face of the user. The materials, in contact with the user's skin, are suitable for medical use, and do not contain latex.

Thanks to its efficiency of bacterial filtration (BFE)>98% it can help to reduce the risk of respiratory diseases in work environments, at home or in group.

CUSTOMIZATION

The MSK.P mask is customized with company logos or other small graphic decorations requested by the client. The printing is placed on the outer side of the mask (the one not in contact with the skin of the user) in a print area of 58 x 18 mm. In order to ensure compliance of the medical device with the ISO standard 10993-1 have been conducted a careful risk analysis, a selection of components and materials (including printing pigments) from the design phase. The validation of the correct design has been conducted through laboratory analyzes suitable for demonstrate compliance of the customized medical device with ISO 10993-1.

SIZE

≈ mm 175x94 referred to the filtering part, not including the elastic bands.

PACKAGING

Each box contains 36 packages of 10 MASKITA® each.

Each package of 10 pieces is properly labeled with identification code and instructions.

CONSERVATION

Store in a cool, dry place far from any source of heat or naked flams.

Keep away from intense exposure to the sun or direct lighting.

DISPOSAL

After use throw the masks away in a specific closable container and sanitize your hands carefully. Do not litter it in the natural environment. Disposal must be carried out in accordance with current regulations.

WARNINGS

Not suitable for children.

Do not wash, do not reuse and do not use for other purposes.

To date there are no know hypersensitivity skin reactions if the medical advice are properly used. In the event of skin reactions appearance discontinue use immediately and notify to info@maskita.eu

Data and information in this technical data sheet are based on the knowledge available at the date of issue: the user must ensure the adequacy and completeness of the information in relation to its use.