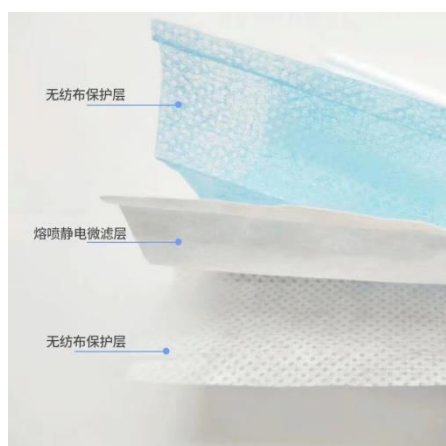


MASCHERINA FACCIALE MONOUSO



Mascherina facciale monouso realizzata con 3 strati :

22gr di PP + 25 gr di filtro + 25 gr di PP



Clip metallica sul naso per una miglior vestibilità ed aderenza al viso

Testata e conforme agli standard europei 93/42/CEE inclusa direttiva 2007/47/EC

Confezione da 50 pezzi

Istruzioni per l'uso

1. Utilizzare la maschera con la pelle asciutta.
2. Appoggiare la maschera al viso utilizzando i lacci laterali, la parte in alluminio deve stare sopra il naso.
3. Regolare l'occhiello attorno alle 2 orecchie in modo da tenere la maschera ferma.
4. Regolare la dimensione della maschera per coprire completamente la bocca e il naso.
5. Premere la parte in alluminio della maschera sul naso in modo che si adatti alla forma del viso.



Compliance Report

Applicant: XIANTAO GENERALCARE PROTECTION PRODUCTS CO.,LTD.
Address: 9D, HUANGJIN VILLAGE, XIANTAO CITY, HUBEI, CHINA.
Product: Face Mask, Dust Mask, Disposable Apparel, Protection Gown, Isolation Gown, Surgical Gown, Lab Coat, Raincoat, Visitor Gown, Coverall, Kimono, Pants, Apron, Shoe Cover, Beard Cover, Sleeve Cover, Boot Cover, Disposable Cap, Bouffant Cap, Clip Cap, Disposable Glove, Disposable Liner, Disposable Cover, Bed Sheet, Bed Cover, Pillow Cover, Shopping Bag, Slipper, Bra
Type: See annex for details
Product Classification: Class I

The submitted technical files including test report of the above products have been reviewed against the self declaration requirements of conformity for CE marking according to Annex I & VII of the 93/42/EEC Medical Device Directive (including 2007/47/EC).

The review result of the technical files and test report support the self declaration for the devices listed above. The test report and the technical files are the annex of this report and should be used together.

Where the manufacturer affix's the CE marking to the product listed they must ensure that all the requirements of the appropriate EU directive(s) have and continue to be met.

This report is not a certificate of conformity.

No. 02709

Initial Issue Date: 15 May 2017

Tony Chen

General Manager (Signature)

CERTIFICATE OF ACCREDITATION



Quality Management System

Registration No. 63486Q80324ROS

We hereby certify that
Xiantao GeneralCare Protection Products Co.,Ltd

9D Huangjin Village, Xiantao, Hubei, China, 433000

Established quality management system

ISO 13485:2016

Scope of certification/registration

disposable face mask, shoe covers, caps, sleeve cover, aprons, beard covers, disposable cover, pants, gloves, apparels and other related products

Issue date of this certificate: Dec 02, 2019 Valid date of this certificate: Dec 01, 2020

First registration: Dec 02, 2019 ~ Registration deadline: Dec 01, 2022

(The effectiveness of this certificate shall be validated by periodic surveillance audit of ISP for maintenance.
The intervals of not more than 12 months, Conditions on effectiveness of certificate see <http://www.isp-acpc.com>
Note: the use of outside mainland China)



Issued by:



INSPEC INTERNATIONAL
www.isp-acpc.com