

Distribuito



Oferta semimasca faciala import CHINA

Pret partener – 5 lei fara tva/minim 300bucati

Atentie!!! Acest produs nu inlocuieste o masca medicala cu filtre speciale integrate! Acest produs nu este un dispozitiv medical! SC Iftode Universal Srl nu isi asuma raspunderea pentru eventualele situatii de imbolnavire!

Pentru o protectie cat mai buna, semimasca de protectie trebuie sa se potriveasca in mod corespunzator fetei utilizatorului.

Cu stima, George Namolosu, 0749203585, Iftode Universal Galati



STOC LIMITAT.

PERSONAL NU AM INCREDERE in ce este acum pe piata, dar decat NIMIC, aduc si eu la cunostinta produse ce le gasim disponibile!

Distribuito

Iftode Universal
sisteme de construcții

Declaration of Conformity

CE 符合性聲明

Declaration of Conformity

CE Declaration of Conformity CE

CE 符合性聲明

According to the Medical Device Directive 93/42/EEC

按照医疗器械指令 93/42/EEC

Manufacturer:

Authorized Representative: Name:
授权代表 Address:

Medical Device:
医疗器械

Product Name:

DISPOSABLE STERILIZATION POUCHES/ROLLS

一次性使用灭菌包装

MEDICAL CREPE PAPER/ROLL

皱纹纸/卷

SMS NON-WOVEN STERILIZATION WRAP

无纺布

STERILIZATION INDICATOR TAPE/STRIP

灭菌指示胶带/指示卡

BOWIE-DICK TEST PACK

B-D 测试包

DISPOSABLE MEDICAL FACE MASK

一次性医用口罩

MDD-Classification:
MDD-分类

Class I
级别 I

The undersigned hereby declares that the medical device as specified above conforms with the essential requirements listed in the Annex 1 of the European Medical Device Directive 93/42/EEC(MDD).Applying ISO13485:2003 Medical Devices - Quality Management Systems and the production is in accordance with EN868 and ISO11607. The Items above are all Non-Sterile before shipping.

兹签字声明以上所列医疗器械符合欧洲医疗器械指令 93/42/EEC(MDD)附件 1 列明的必要要求。适用 ISO13485:2003 医疗器械-质量管理体系,并依照欧洲标准 EN868 和国际标准 ISO11607 生产。

This declaration of conformity is based on the European Medical Device Directive 93/42/EEC,Annex<V> and is supported by The Certification Body Of TUV PRODUCT SERVICE GMBH,with reference to articles 1 and 3 of the MDD.

参照 MDD 第 1 款和第 3 款,这份符合性声明是基于欧洲医疗器械指令 93/42/EEC 附件(V)设立,并受南德意志 TUV 认证方的支持。

General Manager:

总经理

龙其成

(Place and date of issue)

(Name and signature or equivalent
Marking of authorized person)

Distribuator



Certificate of Analysis

Earloop Procedure Face Mask – Level 1 Barrier Protection

Intended Use:	The procedure medical masks are intended to be worn by personnel during medical procedures to protect both the patient and the operating personnel from transfer or microorganisms, body fluids and particulate material transfer.
Item Code	
Country of Origin	Made in China
Material components	Mask Body Composition Outer Material – Spunbond Polypropylene (25+/-2gsm) Filter Layer – Meltblown Media (25+/-2gsm) Inner Material – Spunbond Polypropylene (25+/-2gsm) Nose-piece Composition - Plastic Covered Iron Earloop strips – elastic spandex Latex Free
Color	Blue
Usage	For Single-use only
Body Size	Length: 175 mm Width: 95mm
Bacterial Filtration Efficiency (BFE)	BFE @ 3.0 μm large bacteria $\geq 95\%$
Differential Pressure (ΔP)	$\Delta P < 4.0 \text{ mm of H}_2\text{O/cm}^2$
Fluid Resistance	Resistant @ 80mmHg
Particulate Filtration Efficiency (PFE)	$\geq 95\%$ with 0.1 μm large particles
Other Tests	
Skin Irritation	Negligible
Skin Sensitization	Negligible
Packaging	50 masks per box, 40 boxes per case, masks/case Boxes are made of cardboard Shipper case is made of corrugated fiberboard
Storage	Store under cool, dry conditions. Avoid excessive heat (over 40°C or 104°F).