

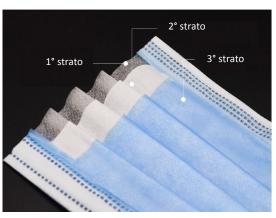
SCHEDA TECNICA

Rev. 03 del 05/2020

Mascherina chirurgica con elastici 3 strati in TNT

DM. CL I

CND T020601











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PRODOTTO IN CINA

CMC Medical Devices & Drugs S.L.
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IMPORTATO DA:

COMITEK HOSPITAL PRODUCTS S.r.I VIA URBANIA 7 - 48018 Faenza (RA) Tel. +39 0546 46502 Mail info@comitekhp.com

SMALTIMENTO:

eguire le normative di legge in materia di smaltimento di rifiuti ospedalieri.

STOCCAGGIO:

Normali procedure di immagazzinamento, tenere in un luogo pulito e asciutto lontanto da fonti di calore.Rispettare i limiti di temperatura indicati in etichetta. CODICE MASC3S

RDM. 1953211

Mascherina chirurgica con elastici 3 strati in TNT . Ogni strato ha una specifica funzione protettiva per permettere alla respirazione un differenziale di pressione ottimale.

- Il primo strato "Out Facing" esterno è realizzato con TNT soffice per un contatto epidermico ottimale.
- Il secondo strato "Filter Medio" realizzato con fibre di polipropilene poliestere con assenza assoluta di fibre di vetro, serve da efficace filtrante ai batteri (BFE) superiore al 96%.
- Il terzo strato "Inner Facing" strato interno ha funzione di contenimento del filtro oltre ad una ulteriore protezione batterica e assorbente del vapore acque.

Destinazione D'uso: Dotazione per il personale Medico e paramedico nel corso di procedure chirurgiche, onde assicurare al paziente una protezione da agenti microbici

Composizione: TNT

Cellulosa - Poliestere - Viscosa

Avvertenze: Il prodotto non è sterile. Maneggiare con cura per non danneggiare la barretta stringi naso. Conservare in luogo asciutto al riparo dalla luce a temperatura ambiente.

2 ANNI DI SCADENZA DALLA DATA DI PRODUZIONE

DIRETTIVA DI RIFERIMENTO : MDD 93/42/ECC Annex VII

EN ISO 13485:2016, EN 14683:2014,

RELATED EN ISO 10993-1, EN ISO 10993,

STANDARDS: EN ISO 10993-10, EN ISO 11737-1, ISO 22609,

EN 1041:2008, EN ISO 14971:2012

CONFEZIONAMENTO					
BUSTA	CARTONE				
50 pz TOTALE PZ PER CARTONE 2.000	MISURA SCATOLA 20 x 11.5 x 8.5 MISURA CARTONE 60 x 42 x 37 40 scatole da 50 pz				





CE

DISPOSABLE MEDICAL FACE MASK

Product name: Disposable Medical Face Mask Specifications: Flat type 17.5cm×9.5cm

Structural composition: Disposable Medical Face Mask consists of a mask body, a nose clip, and a mask band. Product is supplied in non-sterile form.

Application: It is worn by clinical staff during non-invasive procedures, covering the user's mouth, nose, and jaw, providing a certain physical barrier to prevent direct penetration of pathogenic microorganisms, particulate matter, in patients, etc.

Instructions for user:

- 1. Open the product packaging, place the mask with the nose clip facing outward and the white side inward, and gently pull the ear strap to hang the mask on both ears;
- 2. Gently press the nose clip to fit it to the bridge of the nose, bend and adjust the nose clip, then press and hold the nose clip, and pull the lower end of the mask to the jaw;
- 3. Keep the mask close to the face and stretch the mask so that it completely covers the mouth, nose and chin, and check the tightness of the edges to obtain the best protection effect;
- 4. When discarding, fold the mask from the inside to the outside to cover the fixing sheet, and bind it with a strap before throwing it into an unrecyclable garbage bin to avoid polluting the environment.

Product performance: The bacterial filtration efficiency of the mask should be not less than 95%. **Contraindications:** Those who are allergic to the ingredients of this product are prohibited.

Warnings

- 1. This is a disposable product.
- 2.Do not reuse. Reusing may cause cross-contamination.
- 3.The products should be stored in dry and cool conditions and without sunlight. Do not use it if with damage to the packing.
- 4.This product should be disposed and destroyed according to the management requirements of medical waste. Avoid pollution to the environment.

Storage and transportation conditions: Store at room temperature, the relative humidity should not exceed 80%, non-corrosive gas and well-ventilated room. Transportation means should be clean and isolated from fire sources.

Sample drawings of labels and packaging marks:

⊗No reuse ☐	Consult inst	ructions for	use	∆ Caution	Use-by date	LOT Batch code
Date of manak	kacture Th	Keep dry	淤 Ke	ep away from	sunlight	

Shelf life: Two years

Manufacture date: Packing against order

Registrant / Manufacturer: Shandong Haidike Medical Products Co.,Ltd.

Registrant / Manufacturer address: Tianfu Road, Dongcheng District, Shan County, Heze City, Shandong Province, China.

Address: Tianfu Road, Dongcheng District, Shan County, Heze City, Shandong Province, China.

Tel: +86-530-4660062

After-sales service company: Shandong Haidike Medical Products Co.,Ltd.

Tel: +86-530-4660062

E-mail: info@suturescn.com

ECIREP CMC Medical Devices & Drugs S.L.

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Email: info@cmcmedicaldevices.com



CERTIFICATE FOR MEDICAL DEVICE

Declaration of Conformity

Version number: A/0 Certificate No.: HDK-010-030220R

Company Name: Shandong Haidike Medical Products Co., Ltd.

Tianfu Road, Dongcheng District, Shan County, 274300 Heze City, Company Address:

Shandong Province, China.

MDD 93/42/EEC Medical Device Directive/Annex VII Related Directives and Annex

Class I Non Sterile

EN ISO 13485:2016, EN14683:2014, ENISO10993-1, ENISO10993, Related Standards

ENISO10993-10, ENISO11737-1, ISO22609, EN 1041:2008, EN ISO

14971:2012

Products Name Face Masks

Earloop flat type: 12.5×9cm, 14.5×9.5cm, 16.5×9.5cm. 17.5×9.5cm

Vertical type: 1/2 DxL: 9cm×10cm, 9cm×11cm, 10cm×11cm,

10cm×12cm, 11cm×12cm, 11cm×13cm, 11.5cm×13cm, 12cm×13cm,

12cm×14cm, 11.5cm×15cm

CMC Medical Devices & Drugs 5.L.

Add: C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain

European Authorized Tel: +34 951 214 054 Representative:

Contact: Manuel Mateos

Email: info@cmcmedicaldevices.com

Effective Date March 2nd, 2020

The products satisfies the requirements of the above listed standards. The Manufacturer is responsible for carrying out all the necessary activites as required by the Directive.

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Product Model/Type

Knyket

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