

Surgical Mask

1) Brand: Esound Med

2) Standard: YY0469-2011

3) Information:

(1) Filtration Material: Polypropylene melt-blown nonwoven; three layers

(2) Bacteria Filtration Efficiency: $BFE \geq 95\%$

(3) Application: Designed for the general protection for public health workers or relative persons, as well as the isolation of body liquid and splash risk during Invasive manipulation .

(4) Sterilization: Sterile, Ethylene Oxide Process. No reuse.

(5) Testing Report: CMA certificated testing laboratory

(6) Meets the technical requirements for CE

(7) Package &Weight

- Package: 20 pcs/bag; 200pcs/box, 4000 pcs/Carton
- Gross Weight: 17kg/carton
- Size: 64cmX49cmX53cm (carton)

4) CE CERTIFICATE



CERTIFICATE
of conformity

93/42/EEC
Certificate No. 005011171025K
E.Sound Medical Device Co., Ltd
Changyuan County High-tech Medical Equipment Industrial Park

Holder:

Product Description:
Disposable Nasal Oxygen Tube, Endotracheal Tube, Reinforced Endotracheal Tube, Disposable Nasogastric Feeding Tube, Disposable Urinary Catheter, Disposable Medical Oxygen Mask, Disposable Laryngoscope Blade, Disposable Medical Mask, Medical Surgical Mask, Medical Protective Masks, Disposable Medical Cap, Disposable Therapeutic Towel, Medical Nursing Pad, Disposable Surgical Drape, Medical Disposable Protective Clothing, Medical Skin Gases Block, Medical Absorbent Gauze Pad, Disposable Sterile Surgical Film, Disposable ECG Electrode, Disposable PE Examination Gloves, Sterile Dressing, Disposable Medical Jet Nebulizer, Medical Teeth Pad, Disposable Medical Anesthesia Face Mask, Breathing System Filters for Anesthetic and Respiratory, Laryngeal Mask, Medical Cotton Swab, Disposable Sterile Dressing, Disposable Medical Mask and Cap, Disposable Surgical Drape with Hole, Disposable Surgical Shaving Prep Kit, Disposable Wound Dressing Kit, Disposable Oral Cavity Kit, Disposable Dialysis Care Kit, Disposable Nasogastric Feeding Tube, Disposable Sputum Suction Bag, Disposable Urinary Catheter Tray, Disposable Anesthesia Breathing Circuit, Disposable Endotracheal Tube Tray, Medical Cotton Pad, Disposable Gastric Feeding Tube, Medical Cotton Ball, Medical Skin Gases Block, One-time Use of Sterile Surgical Package, One-time Use of Sterile Production Package, One-time Use of Gastric Tube Components, One-time Use of Tracheal Cannula Assembly, Disposable Medical Laryngeal Mask Assembly, Skin Knife (Non-sterile), Waterproof Wound Pad (Non-sterile), Drainage Bag (Non-sterile), Seal (Non-sterile), Dental Probe (Non-sterile), Spatula (Non-sterile), Surgical Tape, Suction Tube (Non-sterile), Skin Cotton Balls (Non-sterile), Cotton (Non-sterile), Oral Mirror (Non-sterile), Wound Pad (Non-sterile), Mouth Pad (Non-sterile), Gynecological Examination Pad (Non-sterile), Negative Pressure Drainage (Non-sterile), Belt (Non-sterile), Sodium Lime (Non-sterile), Gauze Bandage, Gypsum Bandage (Non-sterile), Washing Clothes (Non-sterile), Disinfecting Brush (Non-sterile), Medical Check Pad (Non-sterile)

Codes/Standards Applied: ES 14076:2003 EN 93 1985-02:2005

Technical Construction File
Report Number: Y3-001

This certificate of conformity is based on the technical construction file. We hereby certify that the above-mentioned product meets the requirements of 93/42/EEC.

Applied Codes And Standards:


David Smith
Manager



ETL
15A LANCHESTER WAY ROYAL OAK INDUSTRIAL ESTATE
DAVENTRY NORTHAMPTONSHIRE ENGLAND NN11 8PH
WWW.UKESC.ORG.UK
E-MAIL: INFO@UKESC.ORG.UK

Date Of Issuance : Oct.25, 2017
Date Of Validity : Oct.24, 2020

certificate

5) CE Conformity

International Certification Registrar - International Certification Registrar



Attestation of Conformity

No. ICR Polska/M6101120 **CE**

Name and address of Registered Manufacturer: ESoundMed Medical device Co., Ltd.
High-tech medical equipment industrial park in Changruan County,
China

Product name: Medical Protective Mask

Product type/model: Folded

This Attestation confirms that the product meets the requirements of the following normative documents and within limits of its documents gives presumption of conformity with essential requirements of Directive 93/42/EEC.

Relevant EC Directive: Medical Device Directive 93/42/EEC

Conformity assessment procedure: EC Declaration of Conformity (Annex VII of Directive 93/42/EEC)

Classification: Class I according Rule 1 of Annex IX of Directive 93/42/EEC

Applied normative documents: EN 14683:2019
EN ISO 10993-11:2018

Applied Quality Management System EN ISO 13485:2016

This AoC will remain valid only if Quality Management System Certificate remains valid and the surveillance audits are conducted.
The assessment process has been carried out in accordance with the program PC-P-07-07.
Evaluation has been carried out in accordance with test reports made by Shanghai MICEZ Equipment Testing & Technical Co., LTD Laboratory.

No. of test report: MICEZ-2020-030902-MDD
1103.2020

Issue date: 1103.2020

Expiration date: 1003.2025

The mutual obligations and rights of the certification are regulated by the contract No. ICR Polska/2020-1011.

This Attestation applies to products having the same attributes (parameters), intended use, that have been evaluated and meet the requirements of the aforementioned standards.



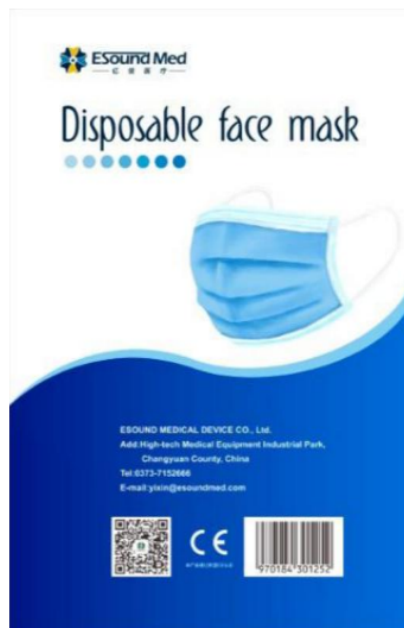
Director: Rafal Kalinowski

Warsaw, 11. 03. 2020.

ICR Polska Co. Ltd.
ul. Plac Przymierza 6, 03-944 Warszawa
www.icrpolska.com, e-mail: icrpolska@icrpa.com



6) Product Picture



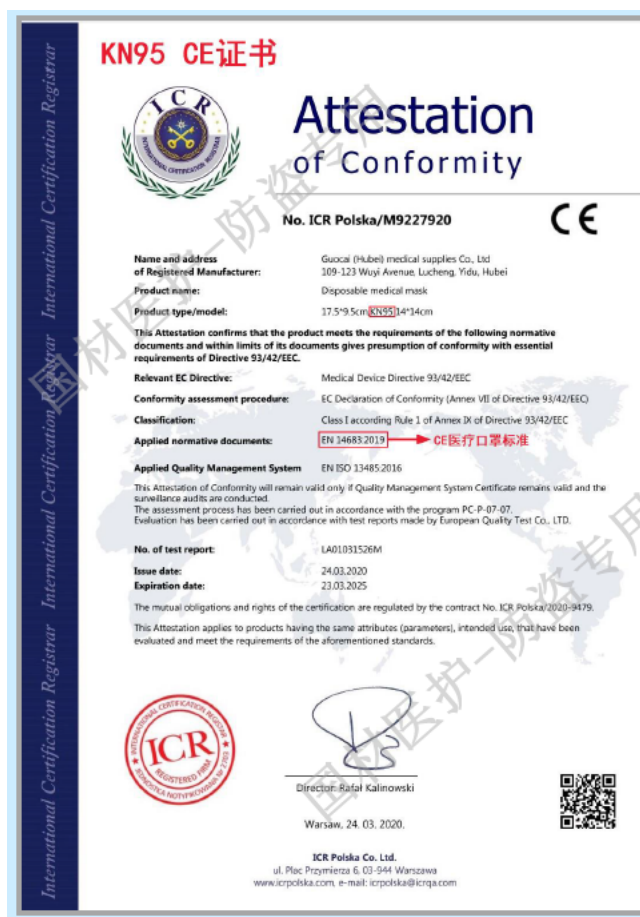


1. KN95 Mask

1) Brand: GuoCai

2) Standard: GB2626-2006

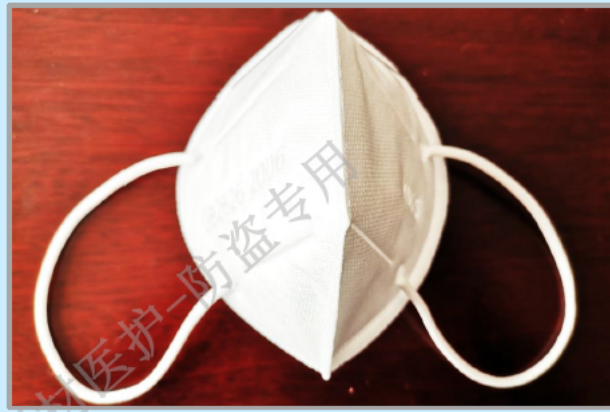
3) CE CERTIFICATE



4) Product picture

50个/盒





中国医药集团

医用口罩(含普通、KN95)

国材医药有限公司

防控疫情·我们在一起

真正有效防护

TRUE EFFECTIVE PROTECTION

防护
舒适

透气
性好

防尘
防霉

