



EVEREAST MEDICAL PRODUCTS GROUP CO., LTD.
Add: No.1 Wangzhuang Village, Shejia Town, Changyuan County, Henan 453400, China
Tel: 0086 371 5598 9823 Fax: 0086 373 8949777

Declaration of Conformity

Manufacturer:

Name: Evereast Medical Products Group Co., Ltd.

Add: No.1 Wangzhuang Village, Shejia Town, 453400 Changyuan County, PEOPLE'S REPUBLIC OF CHINA

Tel: +86(373) 5598 9823 Fax: +86(373) 8949777

European Representative:

Name: Shanghai International Holding Corp. GmbH (Europe)

Address: Eiffestrasse 80, 20537 Hamburg, Germany

Product Name: Disposable Sterile Surgical Mask

Class: I Sterile

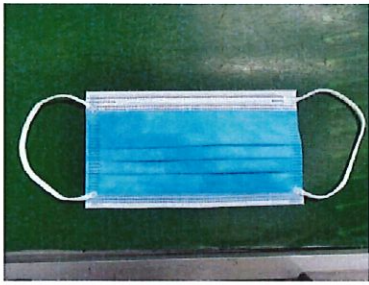
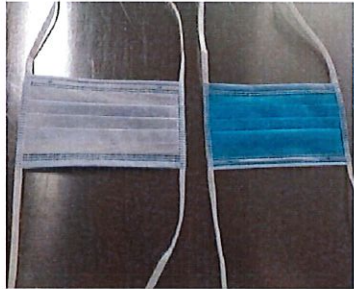
UMDNS Code: 12458

Size: 17.5cm×17cm

Intended Use:

Disposable sterile surgical mask helps reduce exposure of the patient and health care professional to potential infectious airborne particulate hazards.

Model:

Ear loop	Tie on
	

Classification and relevant Rule of MDD: Annex IX I, Rule 1

Conformity Assessment Route: MDD 93/42/EEC Annex V

Different models depend on the customer's specific requirements and no clinical manifestation difference.

We herewith declare that the above mentioned products meet the provisions of the following EC Council Directives and Standards. All technical documentations are retained under the promises of the manufacturer.

Eveeast Medical Products Group Co., Ltd. is exclusively responsible for the declaration of conformity.



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DIRECTIVES

Medical Device Directive:

1. COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES (MDD 93/42/EEC)
2. The product meets the provisions of EN14683:2019

Type IIR



Notified Body:

TÜV SÜD Product Service GmbH Ridlerstr.65, 80339 München, Germany

Notify Body CE 0123, CE Certificate No.: GZS 0959169006 Rev. 00, Valid until: 2022-03-12

Signature of issue person:

长东医疗器械集团有限公司
EVEREAST MEDICAL PRODUCTS GROUP CO., LTD.

Position: General Manager

Name:

杨国林

Date: 2020-03-23

Place: Xinxiang