



NINGBO HI-TECH UNICMED IMP. & EXP. CO., LTD

Add: 11/F, Green Town Lvyuan Tower, No. 588 Canghai Road, Ningbo, China 315040
<http://www.unimed.com>
Tel: +86-574-8764 1261/ 8764 0975
8764 0976/ 8764 2798
Fax: +86-574-8764 1260
E-mail: info@unimed.com

EU Declaration of Conformity

Manufacturer:

Name: Ningbo Hi-Tech Unimed Imp. & Exp. Co., Ltd.
Add: 11/F, Green Town Lvyuan Tower, No.588 Canghai Road,
Ningbo, China

European Representative:

Name: Shanghai International Holding Corp. GmbH(Europe)
Add: Eiffestrasse 80.20537 Hamburg, Germany

Product Name: First Aid Mask

Trade name /Trademark: N.A.

Object of the declaration:

SRN: Not yet

Intended purpose:

First Aid Mask is intended for cardiopulmonary resuscitation and are used to isolate emergency personnel from the victim's mouth and prevent cross infection.

UMDNS Code: 12-448

Basic UDI-DI: 6974495691005023M

Classification (MDR, Annex VIII): I, rule 1

Conformity Assessment Route: Article 19 +Annex II+III

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the Regulation (EU)2017/745 on Medical Devices (MDR). All supporting documentations are retained under the premises of the manufacturer.

REGULATIONS

General applicable regulations:

Medical Device Regulation: REGULATION (EU) 2017/745

Place of Issue: Ningbo, CHINA

Date of Issue: 2021-06-15

Signature: Mr. Honghao Zhou

Position: General Manager

