



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

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EU Declaration of Conformity

Manufacturer:

Name: Ningbo Hi-Tech Unicmed 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: Face Mask

Code Number: 500029

SRN: Not yet

Intended purpose: The Face Masks are intended to be worn to protect both the patient and healthcare personnel from transfer of microorganisms, body fluids and particulate material.

GMDNS Code: 35177

Basic UDI-DI: 6974495690102002Y

Classification: I, Rule I

Rule: Rule 1, Annex VIII, Regulation (EU) 2017/745

Conformity Assessment: Annex II+III of Regulation (EU) 2017/745

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: 2021-11-11

Signature: Mr. Honghao Zhou

Position: General Manager

