



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

11/F,Green Town Lvyuan Tower, 588 Canghai Road, Ningbo, China

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Declaration of Conformity

Manufacturer: Ningbo Hi-tech Unicmed Imp. & Exp. Co., Ltd
11/F, Green Town Lvyuan Tower, 588 Canghai Road, Ningbo, China 315040
European Repr- Shanghai International Holding Corp. GmbH(Europe)
Sentative: Eiffestrasse 80, 20537, Hamburg, Germany

Product Name	UMDNS Code	Classification (MDD, Annex IX)
Oxygen Mask with Reservoir bag	12450	II a , rule 2
Nasal Cannula	12700	II a, rule 2
Simple Oxygen Mask	12448	II a, rule 2
Nebulizer Mask	12449	II a, rule 2

Conformity/ Assessment Route: Annex V.3

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

Directives

General Applicable Directive:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC.)

All applicable harmonized standard(published in the Official Journal of the European Communities)

Notify Body: TÜV Product Service GmbH
Ridlerstr. 65, 80339, München, Germany

Identification number: CE0123
(EC) Certificate(s): No.G2 074897 0011 Rev.02

Expire date of the Certificate: 2024-05-26

Start of CE Marking:2019-9-23

Place, Date of Issue: Ningbo, 2019-11-06

Signature: 
Name: Zhou Honghao Position: Managing Director

