

EU DECLARATION OF CONFORMITY

The present declaration is in conformity with this regulation and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity

Manufacturer Shenzhen IMDK Medical Technology Co., Ltd

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Zhenmei Community, Xinhua Street, Guangming District, 518107 Shenzhen,
PEOPLE'S REPUBLIC OF CHINA

Single Registration Number (SRN):CN-MF-000024290

Authorized Representative: MedNet EC-REP GmbH
Borkstraße, 10 48163 Münster, Germany

SRN Authorized Representative: DE-AR-000000002

Product Identification

Product/Trade Name: Portable Mesh Nebulizer
Model: YM-3R9,YM-3R6,YM-3R7,YM-3R8, YM-3R9L, YM-3R8L, YM-3R6L
Basic UDI-DI: 697391294301NEB4M

Product Code

GMDN Code: 35457
GMDN Term: Benchtop nebulizer, non-heated
EMDN Code/CDN code: R03010302
EMDN Term/CDN Term: AEROSOL PORTABLE INHALERS

Classification

Risk Class: class IIa, rule 20
(according to Annex VIII Medical Device Regulation (EU) 2017/745)

Conformity assessment Route: Annex IX chapter I + chapter III of Regulation (EU) 2017/745

We (Shenzhen IMDK Medical Technology Co., Ltd) declare that the above medical device is at our sole responsibility the state medical device (Model: YM-3R9,YM-3R6,YM-3R7,YM-3R8, YM-3R9L, YM-3R8L, YM-3R6L) in conformity with the following legislation(s):

Regulation (EU) 2017/745 of the European Parliament and of the council of 5 April 2017 on medical devices

The conformity of the quality management system according to Annex IX and Article 52 is certified by the following notified body:

TÜV SÜD Product Service GmbH
Zertifizierstellen Ridlerstraße 65
80339 MÜNCHEN
Germany

The identification number of the notified body for implementation of the procedure set out in Annex IX and Article 52 to the above regulation is: 0123

Certificate number of issued certificate: [G15 002145 0007 Rev. 00](#)

Reference to Common Specifications: /

This declaration of conformity is issued under the sole responsibility of Shenzhen IMDK Medical Technology Co., Ltd

This declaration supersedes any declaration issued previously for the same product.

Place and date < Shenzhen, [2025/10/23](#)>

Signature



Name

Yuan Xia

Position

Person Responsible for Regulatory Compliance

Signature



Name

ChangChun Xia

Position

General Manager