

EU DECLARATION OF CONFORMITY

Manufacturer Shenzhen IMDK Medical Technology CO., Ltd.
904, 9F, Guangming Tianan Cloud Park Building, 255 Zhenmei Road,
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

SRN Authorized Representative: DE-AR-000000002

Product Identification

Product/Trade Name: Pulse oximeter
Model: C101H1, C101A2, PO-A2AO, PO-A2AT, PO-A3AO, PO-H1AO, PO-B1AO, PO-C5AO, PO-C5AT, PO-C6AO, PO-C6AT
Basic UDI-DI: 697391294101PO8Z

Product Code

GMDN Code: 45607
GMDN Term: oximeter
EMDN Code/CDN code: Z1203020408
EMDN Term/CDN Term: PULSE OXIMETERS

Classification

Risk Class: class II a, Rule 10
(according to rule 10 of 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: C101H1, C101A2, PO-A2AO, PO-A2AT, PO-A3AO, PO-H1AO, PO-B1AO, PO-C5AO, PO-C5AT, PO-C6AO, PO-C6AT) 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: Not yet
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, 2023/5/26>

Signature



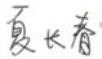
Name

Yuan Xia

Position

Person Responsible for Regulatory Compliance

Signature



Name

ChangChun Xia

Position

General Manager