

EU DECLARATION OF CONFORMITY

Name and address of the manufacturer: **Shenzhen Viatom Technology Co., Ltd.
4E, Building 3, Tingwei Industrial Park,
No.6 Liufang Road, Block 67, Xin'an Street,
Baoan District, 518101 Shenzhen, P.R.China**

SRN (Manufacturer) **CN-MF-000012182**

Name and address of Authorized Representative: **MedNet EC-REP GmbH
Borkstrasse 10 , 48163 Muenster, Germany
Telefon: +49 251 32266-61
Telefax: +49 251 32266-22**

SRN (EU Authorised) **DE-AR-000000002**

We declare that the product concerned has been designed and manufactured under a quality management system according to Regulation EU 2017/745(MDR) Article 120, Annex II of 93/42/EEC and Regulation (EU) 2023/607.

Medical Device: **Pulse Oximeter
Model: PO2,PO4**

Intended use/purpose: **This Pulse Oximeter is intended to be used for measuring, displaying and storing adult' s pulse oxygen saturation (SpO2), pulse rate of adults in home or healthcare facilities environment.**

GMDN **45607 Pulse oximeter, battery-powered**
Risk class: **Class IIa**
Basic UDI-DI **/**

Conformity assessment procedure: **MDD 93/42/EEC Annex II excluding (4)**

The EU declaration of conformity is issued under sole responsibility of the manufacturer. We hereby declare that the above mentioned products meet the provisions of the following EUROPEAN PARLIAMENT AND OF THE COUNCIL Regulation and Applicable standards. All supporting documents are retained under the premises of the manufacturer.

Regulations **EU 2017/745 (MDR) Article 120
93/42/EEC
Regulation (EU) 2023/607
RED, 2014/53/EU**

Applicable CS or Standard(s) **IEC 60601-1:2005+A1:2012+A2:2020
EN 60601-1-2:2015+A1:2021
EN 60601-1-6:2010+A2:2021
EN 60601-1-11:2015+A1:2021
EN ISO 80601-2-61:2019 EN ISO 10993-1:2020
EN ISO 10993-5:2009 EN ISO 10993-10:2013
EN ISO 15223-1:2021 EN ISO 14971:2019/A11:2021
EN ISO 20417:2021 EN 62479:2010
EN 50663:2017
ETSI EN 300 328 V2.2.2(2019-07)
ETSI EN 301 489-1 V2.2.3 (2019-11)
ETSI EN 301 489-17 V3.2.4 (2020-09)**

Certificate No.: **HD601373560001**

Issue date: **2019-07-17**

Expiry date: **2024-05-27**

Notified Body: **TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg
Deutschland
CE 0197**

Shenzhen, 2023/05/19
Place, date

Zhou Saixin General manager
Name and function

