

EU DECLARATION OF CONFORMITY

Name and address of the manufacturer: **Shenzhen Viatom Technology Co., Ltd.
901, Building West, Lepu Tower, No.66 Xingke Road, Xili Community, Xili Street, Nanshan District, Shenzhen, 518055, Guangdong, P.R. China**

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

Name and address of Authorized Representative: **MedNet EC-REP GmbH
Borkstrasse 10 , 48163 Muenster, Germany**

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: PF-10AW, PF-10A, PF-10AW1, PF-10A1, PF-10BW, PF-10B, PF-10BW1, PF-10B1, PF-20AW, PF-20AW1, PF-20B, PF-20B1**

Intended use/purpose: **This Pulse Oximeter is intended to be used for measuring, displaying and storing of pulse oxygen saturation (SpO₂), pulse rate of patients in home or health care 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**

Applicable CS or Standard(s) **EN 60601-1:2006+A1:2013+AC:2014+A12:2014+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 10993-1:2018
EN ISO 10993-5:2009 EN ISO 10993-10:2010
EN ISO 15223-1:2021 EN ISO 20417:2021
EN ISO 14971: 2019 EN 50663:2017
EN 301 489-1 V2.2.3 EN 301 489-17 V3.2.4
EN 300 328 V2.2.2**

Certificate No.: **HD601373560001**

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

Expiry date:

2028-12-31

Notified Body:

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

Shenzhen, 2025/03/31
Place, date



Zhou Saixin General manager
Name and function