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 (Manufucturer)	**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: 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	**69344401PO2ZG**
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:	**2028-12-31**
Notified Body:	**TÜV Rheinland LGA Products GmbH** **Tillystraße 2** **90431 Nürnberg** **Deutschland** **CE 0197**

Shenzhen, 2025/03/31 — Zhou Saixin General manager

Place, date — Name and function