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 (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 Annex IX of EU 2017/745 (MDR).

Medical Device:	**Pulse Oximeter** **Model: PO5, PO5-1, PO5-2, PO5-3**
Intended use/purpose:	**This Pulse Oximeter is intended to be used for measuring, displaying and storing of the pulse oxygen saturation (SpO2), pulse rate of adults, pediatric and infants in home or healthcare facilities environment.**
GMDN	**45607 Pulse oximeter, battery-powered**
Risk class:	**Class IIa**
Basic UDI-DI	**69344401PO5ZN**
Conformity assessment procedure:	**EU 2017/745 (MDR) Annex IX (Chapter I + III and Sec.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)** **RED, 2014/53/EU** **ROHS, (EU) 2015/863** **ROHS, Directive 2011/65/EU**
Applicable CS or Standard(s)	**EN 60601-1:2006/A2:2021** **EN 60601-1-2:2015+A1:2021** **EN 60601-1-6:2010+A2:2021** **EN 60601-1-11:2015/A1:2021** **EN ISO 10993-1:2020** **EN ISO 10993-5:2009** **EN ISO 10993-10:2023** **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)
EN ISO 14971:2019/A11:2021
EN ISO 13485:2016 **EN ISO15223-1: 2021**
EN ISO 20417:2021 **EN 62304:2006+A1:2015**
EN ISO 80601-2-61:2019

Certificate No.: **HZ 2120274-1**

Issue date: **2024-01-18**

Expiry date: **2029-01-17**

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

Shenzhen, 2024/02/23
Place, date

Zhou Saixi General manager
Name and function