

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, 518055 Shenzhen, Guangdong P.R.
China

SRN (Manufacturer)

CN-MF-000012182

Name and address of Authorized
Representative:
SRN (EU Authorised)

MedNet EC-REP GmbH
Borkstrasse 10 , 48163 Muenster, Germany
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

Intended use/purpose:

Model: PO6, PO6A, PO1, PO1B, PO6B, PO6C

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
Risk class:
Basic UDI-DI

45607 Pulse oximeter, battery-powered
Class IIa
/

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, 2025/03/26
Place, date

Zhou Saixin General manager
Name and function

