

# 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**

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 (SpO<sub>2</sub>), 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: **2023-05-24**

TÜV Rheinland LGA Products GmbH • 51105 Köln

*Shenzhen Viatom Technology Co., Ltd.  
4E, Building 3, Tingwei Industrial Park, No.6 Liufang  
Road, Block 67, Xin'an Street, Baoan District,  
Shenzhen, 518101, Guangdong,  
P.R. China*

Contact

Tel. +49 911 655-5225  
Mail: [medical-products@de.tuv.com](mailto:medical-products@de.tuv.com)

Date January 22, 2024

### **Notified Body Confirmation Letter**

Reference. : 10924064

To whom it may concern,

### **Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.**

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Shenzhen Viatom Technology Co., Ltd.  
4E, Building 3, Tingwei Industrial Park, No.6 Liufang  
Road, Block 67, Xin'an Street, Baoan District,  
Shenzhen, 518101, Guangdong,  
P.R. China  
SRN Number (if available): CN-MF-000012182

The devices covered by the formal application and the written agreement mentioned above are identified in the tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by March 20, 2023 for the relevant devices.

TÜV Rheinland  
LGA Products GmbH

Am Grauen Stein  
51105 Köln  
Germany

Headquarter

Tillystraße 2  
90431 Nuremberg

Phone. +49 911 655 5225  
Fax +49 911 655 5226  
[service@de.tuv.com](mailto:service@de.tuv.com)  
[www.tuv.com/safety](http://www.tuv.com/safety)

Board of Management

Dipl.-Ing.  
Thomas Weigand, Spokesman

Dipl.-Kfm.  
Dr. Jörg Schlösser

Nuremberg HRB 26013  
VAT No.: DE 811835490

Chairman of the  
Supervisory Board

Dr.-Ing. Michael Fübi

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body



Samuel Qin  
Certification body

**Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:**

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<b>Vital Signs Monitor</b> Model: Checkme Pro, Checkme Plus, Checkme Pod, Checkme Lite  <b>Basic UDI-DI:</b> 69344401CheckmePro9X	Class IIa	Health Monitor Model: Checkme Pro, Checkme Plus, Checkme Pod, Checkme Lite	Certificate # HD 60137356 0001  NB #0197
<b>Blood Pressure Monitor</b> Model: BP1, BP1A, BP1S, BP1SA, BP1B, BP1C  <b>Basic UDI-DI:</b> 69344401BP1SP8	Class IIa	N/A	Certificate # HD 60137356 0001  NB #0197
<b>Blood Pressure Monitor</b> Model: BP2A  <b>Basic UDI-DI:</b> 69344401BP2AN7	Class IIa	N/A	Certificate # HD 60137356 0001  NB #0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
<b>Pulse Oximeter</b> Model: Oxiband  <b>Basic UDI-DI:</b> 69344401Oxiband29	Class IIa	N/A	Certificate # HD 60137356 0001  NB #0197
<b>Pulse Oximeter</b> Model: PO2, PO4  <b>Basic UDI-DI:</b> 69344401PO2ZG	Class IIa	N/A	Certificate # HD 60137356 0001  NB #0197
<b>Pulse Oximeter</b> Model: PO6, PO6A, PO1, PO1B  <b>Basic UDI-DI:</b> 69344401PO6ZQ	Class IIa	N/A	Certificate # HD 60137356 0001  NB #0197
<b>Pulse Oximeter</b> Model: VTM01, VTM01A, VTM01B  <b>Basic UDI-DI:</b> 69344401VTM01S7	Class IIa	N/A	Certificate # HD 60137356 0001  NB #0197
<b>Pulse Oximeter</b> Model: PO6B, PO6C  <b>Basic UDI-DI:</b> 69344401PO6BRJ	Class IIa	N/A	Certificate # HD 60137356 0001  NB #0197
<b>Pulse Oximeter</b> Model: PF-10AW, PF-10AW1, PF-10A, PF-10A1, PF-10BW, PF-10BW1, PF-10B, PF-10B1  <b>Basic UDI-DI:</b> 69344401PF-10AW9D	Class IIa	N/A	Certificate # HD 60137356 0001  NB #0197
<b>Pulse Oximeter</b> Model: PF-20AW, PF-20AW1, PF-20B, PF-20B1  <b>Basic UDI-DI:</b> 69344401PF-20AW9L	Class IIa	N/A	Certificate # HD 60137356 0001  NB #0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification

**Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:**

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

**Confirmation Letter Revision History**

Date	NB internal reference traceable to each version of the letter	Action
2024-01-22	10924064	Initial issue

Expiry date:

**2024-05-27**

Notified Body:

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

Shenzhen, 2023/11/01

Place, date

Zhou Saixin      General manager

Name and function

