EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60137356 0001

Report No.: 17039584 008

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
China

Products:
- Vital Signs Monitors
- Pulse Oximeters
- Blood Pressure Monitors

Replaces Approval, Registration No.: HD 60123955 0001

Expiry Date: 2024-05-27

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2019-07-17

Date: 2019-07-17

Notified Body

Fuxiu Sheng

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EC 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**
Name and address of Authorized Representative:	**MedNet GmbH** **Borkstrasse 10 · 48163 Muenster · Germany** **TEL: +49 251 32266-0** **FAX: +49 251 32266-22**

We declare under our sole responsibility that

the medical device:	**Pulse Oximeter** **Model:** **Oxiband** **Include accessories** **540-00918-00 SpO2 sensor**
UMDNS of class:	**17148** **Class IIa** according to annex IX of directive 93/42/EEC
Conformity assessment procedure:	**Directive 93/42/EEC Annex II.3**
Registration No.:	**HD 60137356 0001**
Notified Body:	**TÜV Rheinland LGA Products GmbH** **Tillystraße 2** **90431 Nürnberg** **Deutschland** **CE 0197**

Shenzhen, 2019/07/17
Place, date

Management representative Wang Guannan
Name and function