



**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

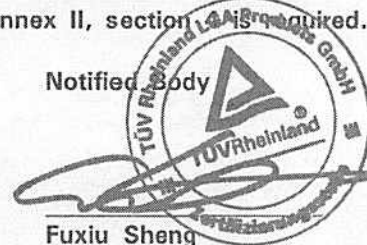
Replaces Approval, Registration No.: HD 60123955 0001

**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 4.18 is required.

**Effective Date:** 2019-07-17

**Date:** 2019-07-17



**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

