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:	**Wireless dynamic multi-parameter holter** **Model: M5, M12, Lepod, Lepod Pro, LMT-5 and LMT-12**
Intended use/purpose:	**The Wireless dynamic multi-parameter holter is a small digital ambulatory ECG recorder, It intended to record, store, display, transfer ECG data, receiving and display blood oxygen(SpO2) and PR(pulse rate) data from the Pulse oximeter(Spo2 Probe). For routine checkups and/or self-monitoring of patients in the clinical setting and/or home settings under professional(e.g. doctor, nurse, family doctor）supervision.** **Clinical setting is only applicable to the general medical clinical setting, not for ICU, Emergency, Intensive care, Surgery, and the clinical setting that must be specifically alarm and analyzed.** **The Wireless dynamic multi-parameter holter does not include analysis, diagnosis and monitoring functions. The device data are given to the doctor or the users.** **The device does no analysis by itself and is intended to be used with a compatible ambulatory ECG (Holter) analysis system (AI-ECG Tracker）which will analyze the recorded data.** **The device data and the data analysis are then reviewed by trained medical personnel for the purpose of forming a clinical diagnosis.** **The device data are used as a base to establish a doctors' diagnosis, but the data are cannot replace the diagnosis result given by a doctor.**
GMDN	**35162 Electrocardiographic ambulatory recorder**
Risk class:	**Class IIa**
Basic UDI-DI	**69344401M12WA**
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 /AM2:2020** **EN 60601-1-2:2015+A1:2021** **EN 60601-1-11:2015/A1:2021** **EN 60601-2-47: 2015** **EN ISO 80601-2-61:2019** **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**
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 Saixin General Manager
Name and function