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:	**ECG recorder** **Model: ER2-S**
Intended use/purpose:	**The ECG recorder is intended to record, display, store and transfer single-channel Electrocardiogram (ECG) rhythms at home or in healthcare environment.** **The device no analysis by itself and is intended to be used with a compatible ambulatory ECG (Holter) analys is 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 is intended for use by adults' health-conscious individuals.** **The device does not include analysis and diagnosis functions.** **The device has not been tested and it is not intended for pediatric use.**
GMDN	**30004 Electrocardiograph, general-purpose**
Risk class:	**Class IIa**
Basic UDI-DI	**69344401ER2-SHM**
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 producets 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/A2:2021** **EN 60601-1-2:2015+A1:2021** **EN 60601-1-6:2010+A2:2021** **EN 60601-1-11:2015/A1:2021** **EN 60601-2-47: 2015** **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