

# 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 Annex IX of EU 2017/745 (MDR).

Medical Device: **Dynamic ECG recorder  
Model: ER1-LW, ER1-LB**

Intended use/purpose: **The Dynamic ECG recorder is intended to measure, review and store adults' ECG data at home or in healthcare environment,  
The device continuously records and stores ECG and activity data for at least 7 days at a time.  
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 (used under the care of a physician). The device data and the data analysis are then reviewed by a trained medical personnel for the purpose of forming a clinical diagnosis.  
The device does not include analysis and diagnosis functions.  
The device has not been tested and it is not intended for pediatric use.**

GMDN **35162 Electrocardiographic ambulatory recorder**

Risk class: **Class IIa**

Basic UDI-DI **69344401ER1-LWER**

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/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 10993-10:2023  
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 ISO 20417:2021  
EN ISO 10993-5:2009  
EN 62479:2010  
EN ISO 15223-1: 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

