

EU DECLARATION OF CONFORMITY

Name and address of the manufacturer: **Shenzhen Viatom Technology Co., Ltd.
901, Building West, Lepu Tower, No.66 Xingke Road, Xili Community, Xili Street, Nanshan District, Shenzhen, 518055, Guangdong, 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 Regulation 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) 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 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 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, Directive 2011/65/EU with (EU) 2015/863**

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 62479:2010
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/AC:2018/A11:2021
EN ISO 15223-1: 2021
EN ISO 20417:2021
EN 62304:2006+A1:2015

EN ISO 10993-5:2009

EN 50663:2017

Certificate No.:

HZ 2120274-1

Issue date:

2025-07-07

Expiry date:

2029-01-17

Notified Body:

TÜV Rheinland LGA Products GmbH
Tillystraße 2
90431 Nürnberg
Deutschland
CE 0197

Shenzhen, 2025/7/7
Place, date


Zhou Saixin General manager
Name and function

