# EU DECLARATION OF CONFORMITY

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| Name and address of the manufacturer: | Shenzhen Viatom Technology Co., Ltd.<br>901, Building West, Lepu Tower, No.66 Xingke Road, Xili Community, Xili Street, Nanshan District, Shenzhen, 518055, Guangdong, P.R. China |
| SRN (Manufucturer) | CN-MF-000012182 |
| Name and address of Authorized Representative: | MedNet EC-REP GmbH<br>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).

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| Medical Device: | Blood Pressure Monitor+ECG<br>Model: BP3F, BP3G, HDM3F, HDM3G |
| Intended use/purpose: | The device is intended to measure blood pressure only, electrocardiogram(ECG)only or blood pressure and ECG simultaneously.<br>The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult population.<br>The device is intended to record, store, and transfer single-channel electrocardiogram(ECG),blood pressure and pulse rate.<br>The record data of single-channel electrocardiogram (ECG) from this device in combination with ambulatory ECG (Holter) analysis system (AI-ECG Tracker) can provide recommendations for atrial fibrillation, bradycardia, tachycardia, and sinus rhythm.<br>The device is intended for use by healthcare professionals, and health-conscious individuals in a general household situation.The device has not been tested and it is not intended for pediatric use.<br>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(used under the care of a physician).<br>The device data and the data analysis are then reviewed by a trained medical personnel for the purpose of forming a clinical diagnosis.<br>The device does not include analysis and diagnosis functions. |
| GMDN: | 45617 Automatic-inflation electronic sphygmomanometer, portable,arm/wrist<br>62641 Electrocardiograph, home-use |
| EMDN: | Z1203020302: Non-invasive blood pressure monitoring |

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| | instruments<br>Z120305 ELECTROCARDIOGRAPHS |
| Risk class: | Class IIa according to rule 10(paragraph1,indent 3) |
| Basic UDI-DI | 69344401BP3FNL |
| 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.

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| Regulations | EU 2017/745 (MDR)<br>RED, 2014/53/EU |
| Applicable CS or Standard(s) | EN 60601-1<br>EN 60601-1-2<br>EN 60601-1-11<br>EN 60601-2-47<br>IEC 80601-2-30<br>EN ISO 10993-1<br>EN ISO 10993-5<br>EN ISO 10993-10<br>EN ISO 10993-23<br>EN ISO 14971<br>EN 60601-1-6<br>EN 62366-1<br>EN 62304 |
| Certificate No.: | HZ 2120274-1 |
| Issue date: | 2025-07-28 |
| Expiry date: | 2029-01-17 |
| Notified Body: | TÜV Rheinland LGA Products GmbH<br>Tillystraße 2<br>90431 Nürnberg<br>Deutschland<br>CE 0197 |

Shenzhen, 2025/07/28
Place, date

Zhou Saixin General Manager
Name and position