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 (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 Regulation EU 2017/745(MDR) Article 120, Annex II of 93/42/EEC and Regulation (EU) 2023/607.

Medical Device:	**Vital Signs Monitor** **Model: Checkme Pro, Checkme Plus, Checkme Pod, Checkme Lite**
Attachment / Accessory:	**SpO2 probe (Model: FP10, Part No.:540-00193-00)**
Intended use/purpose:	**The checkme series health monitor is intended to be used for measuring, displaying, reviewing and storing of multiple physiological parameters including ECG, pulse oxygen saturation(SpO2), pulse rate, temperature and blood pressure variation in home or healthcare facilities environment. ECG and Blood pressure variation is intended for use with adults.**
GMDN	**36553 Patient monitor module, multifunction**
Risk class:	**Class IIa**
Basic UDI-DI	**69344401CheckmePro9X**
Conformity assessment procedure:	**MDD 93/42/EEC Annex II excluding (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) Article 120** **93/42/EEC** **Regulation (EU) 2023/607** **RED, 2014/53/EU**
Applicable CS or Standard(s)	**IEC 60601-1:2005+A1:2012+A2:2020** **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 80601-2-56:2017/A1:2020** **EN ISO 80601-2-61:2019** **EN ISO 10993-1:2020** **EN ISO 10993-5:2009** **EN ISO 10993-10:2013** **EN ISO 15223-1:2021** **EN ISO 14971:2019/A11:2021**

EN ISO 20417:2021 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)

Certificate No.:	**HD601373560001**
Issue date:	**2019-07-17**
Expiry date:	**2028-12-31**
Notified Body:	**TÜV Rheinland LGA Products GmbH** **Tillystraße 2** **90431 Nürnberg** **Deutschland** **CE 0197**

Shenzhen, 2025/03/31 Zhou Saixin General manager

Place, date Name and function