

# 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**  
**CN-MF-000012182**

SRN (Manufacturer)

Name and address of Authorized  
Representative:  
SRN (EU Authorised)

**Wellkang Ltd Enterprise Hub, NW Business Complex, 1**  
**Beraghmore Rd. Derry, BT48 8SE, Northern Ireland.**  
**XI-AR-000001836**

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:

**Blood Pressure Monitor**  
**Model: BP2A**

Intended use/purpose:

**This product is intended for use in measuring blood pressure and pulse rate for adult patient population in home and hospital facilities.**

GMDN

**45617 Automatic-inflation electronic**  
**sphygmomanometer, portable, arm/wrist**

Risk class:  
Basic UDI-DI

**Class IIa**  
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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**

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 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: 2024-05-27

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

Shenzhen, 2023/05/24  
Place, date

Zhou Saixin General manager  
Name and function

