

EC 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**

Name and address of Authorized Representative: **WellKang Ltd
Enterprise Hub, NW Business Complex,
1 Beraghmore Road, Derry, BT48 8SE,
Northern Ireland**

We declare that the product concerned has been designed and manufactured under a quality management system according to Annex IX of directive 93/42/EEC.
the medical device:

**Blood Pressure Monitor
Model: BP1, BP1S**

UMDNS of class: **16173
Class IIa**

Applicable Standard(s) **EN 60601-1:2006 /A12:2014 EN 60601-1-2:2015
EN 60601-1-11:2015 IEC 80601-2-30:2018
EN ISO 10993-1:2020 EN ISO 10993-5:2009
EN ISO 10993-10:2013 EN 60601-1-6:2010/A1:2015
EN ISO15223-1: 2021 EN 62366-1: 2015
EN 1041:2008+A1:2013 EN ISO 14971: 2019
EN ISO 13485:2016 EN 50663:2017
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)**

Conformity assessment procedure: **MDD 93/42/EEC Annex II excluding (4)**

Certificate No.: **HD 601373560001**

Issue date: **2019-07-17**

Expiry date: **2024-05-27**

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

This Declaration of Conformity covers all medical devices as specified in the product list belonging to this declaration and is only valid in connection with a batch specific Certificate of Compliance for all products concerned bearing the CE mark.

Shenzhen, 2022/01/17
Place, date

General Manager Zhou Saixin
Name and function

