

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: BP2

UMDNS
of class:

16173
Class IIa

Applicable Standard(s)

EN 60601-1:2006/A2:2021 EN 60601-1-2:2015+A1:2021
EN 60601-1-11:2015/A1:2021 EN 60601-2-47:2015
IEC 80601-2-30:2018 EN ISO 10993-1:2020
EN ISO 10993-5:2009 EN ISO 10993-10:2013
EN 62479:2010 EN 50663:2017
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 EN 1041:2008+A1:2013
IEC62133-2: 2017 EN 60601-1-6:2010/A1:2015
EN 62366-1: 2015 EN ISO15223-1: 2021
EN 62304:2006+A1:2015

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

