TRANSTEK

Manufacturer: Name:Guangdong Transtek Medical Electronics Co.,Ltd

Address: Zone A, No.105 ,Dongli Road, Torch Development District,Zhongshan,Guangdong,China

DECLARATION OF CONFORMITY

We, Guangdong Transtek Medical Electronics Co.,Ltd, hereby declare that the below mentioned medical device —

(i) complies with the requirements under the MDD 93/42/EC;

(A) Particulars of medical device

Generic name:Non-invasive Sphygmomanometer (Blood Pressure Monitor)

Specified name: None

Brand /Model: Medel Elite

Manufacturer: Guangdong Transtek Medical Electronics Co.,Ltd

Country of origin: China

Manufacturing site: Zone A, No.105 ,Dongli Road, Torch Development District, Zhongshan,Guangdong

Classification - Annex IX: class Ⅱa

GMDN code: 16157

Medical device registration number or any approval code: None

(B) Quality Managements System certificate (“QMS”)

Certificate :ISO 13485

Conformity Assessment Body issuing the certificate: TUV

Certificate number: G1 082800 0026Rev.01

Issuance date:2020-03-17

Expiry date: 2024-05-26

(C) Standards Applied

The following harmonized standard is applied to the essential requirement.

EMC	EN 60601-1-2:2015/ IEC 60601-1-2:2014 EN 60601-1-11:2015Clause 12. IEC 60601-1-11:2015 Clause 12, EN 80601-2-30:2010 + A1:2015 Clause 201.17 & 202/ IEC 80601-2-30:2013 Clause201.17 & 202
performance	IEC 80601-2-30:2009/AMD1:2013 for use in conjunction with IEC 60601-1:2005/AMD1:2012
	EN1060-3:1997+A2:2009
	EN ISO 81060-1:2012
safty	IEC 60601-1:2005+A1:2012 IEC60601-1-11:2015
usually	IEC 60601-1-6:2010, AMD1:2013
	IEC62366-1:2015
Rosh	2015/863/EU

I am fully responsible with all the information provided in this declaration. This declaration of conformity is valid from 26th August, 2021.

I fully understand and acknowledge that is an offence under MDD 93/42/EC to make, sign or furnish any declaration, certificate or other document which is untrue, inaccurate or misleading.

Authorised Signatory:

Kevin Tan

/R&D Director

Name/Position

TRANSTEK MEDICAL ELECTRONICS CO.,LTD 广东乐心医疗电子股份有限公司 GUANGDONG

Date:2021-08-27