

EC Declaration of Conformity

Manufacturer:
PIHSIANG MACHINERY MFG. CO., LTD.
No. 108, Hsin-He Road, Hsin-Feng Hsiang 304
Hsinchu County, Taiwan

whose single Authorized Representative:
Wellkang Ltd
Suite B, 29 Harley Street, LONDON W1G 9QR,
England, United Kingdom

We, the manufacturer, herewith declare that the product

Medical Scooter Models: TE-7A

meets the provisions of Directive 93/42/EEC as amended by 2007/47/EC which apply to them.

The medical device has been assigned to class I according to Annex IX of the Directive 93/42/EEC as amended by 2007/47/EC. It bears the mark



The product concerned has been manufactured according to Annex VII of Directive 93/42/EEC as amended by 2007/47/EC.

following the procedure relating to the EC Declaration of Conformity set out in Annex VII of Directive 93/42/EEC as amended by 2007/47/EC.

EN 12184: 2009 Electrically powered wheelchairs, scooters and their chargers – Requirement and test methods

EN ISO 14971: 2012 Medical devices – Application of risk management to medical devices.

EN ISO 14155: 2011 Clinical investigation of medical devices for human subject – Good Clinical practice

EN ISO 15223-1: 2012 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied

The above mentioned declaration of conformity is exclusively under the responsibility of

PIHSIANG MACHINERY MFG. CO., LTD.

Apr. 23, 2015
Date

Maurice Tseng, Technical Manager
Legally binding signature, Function