

# 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: 888WA, 858WM, UL8W12, UL8WFE

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