

## Appendix I

# EC DECLARATION OF CONFORMITY

According to the Medical Device :**93/42/EEC as amended by 2007/47/EC and 93/42/ CEE Annex VII.**

The undersigned, Mr Lee Calvert representing **Dongguan Prestige Sporting Goods Co., Ltd., Manufacture:** No.3 Industry Area, Qiaotou, Houjie Town, Dongguan City, Guangdong Province, 523950, P. R. China, **Head Office:** 27F, No.25, Lane 250, Zhongzheng South Rd., Sanchong District, New Taipei City, 241, Taiwan declares that the scooter described hereafter:

## Scooter

Model identification: **Transformer-S3021**

Provided that is used and maintained in accordance with the generally accepted codes of good practice and the recommendations of the instruction manual, meet the essential safety and health requirements of the Medical Device Directive.the scooters meet the essential requirements set out in Annex I of the MDD 93/42/CEE as well as other requirements in this directive which apply to these products.

For the most specific risks of the scooter safety and reference to the essential requirements of the directive has been on the elements of:

- ✚ EN 1041 2008 : Information supplied by the manufacturer with medical devices
- ✚ EN 980 2008 : Graphical symbols for use in the labeling of the medical devices
- ✚ EN 12184 2009: Electrically powered wheelchairs, scooters and their chargers- requirement and test methods
- ✚ EN 60601-1:2006 General requirements for safety-Collateral standard- Safety requirements for medical device
- ✚ EN 60601-1-2:2007 Medical electrical equipment- General requirements for basic safety and essential performance – Collateral standard Electromagnetic compatibility
- ✚ ISO 13485 2003 : Medical devices - Quality management systems - Requirements for regulatory purposes
- ✚ ISO 14971 2007 : Medical devices - Application of risk management to medical devices
- ✚ ISO 7176-1 1999 : Determination of static stability
- ✚ ISO 7176-2 2001 : Determination of dynamic stability of electric wheelchairs
- ✚ ISO 7176-3 2003 : Determination of efficiency of brakes
- ✚ ISO 7176-4 2008 : Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range
- ✚ ISO 7176-5 2008 : Determination of overall dimensions, mass and turning space
- ✚ ISO 7176-6 2001 : Determination of maximum speed, acceleration and retardation of electric wheelchairs
- ✚ ISO 7176-7 1998 : Measurement of seating and wheel dimensions
- ✚ ISO 7176-8 1998 : Static, impact and fatigue strengths-Requirements and test methods
- ✚ ISO 7176-9 2009 : Climatic test for electric wheelchairs

- ✚ ISO 7176-10 2008 : Determination of the obstacle-climbing of electric wheelchairs
- ✚ ISO 7176-11 1992 : Test dummies
- ✚ ISO 7176-13 1989 : Determination of coefficient of friction of test surfaces
- ✚ ISO 7176-14 2008 : Power and control systems for electric wheelchairs- Requirements and test methods
- ✚ ISO 7176-15 1996 : Requirements for information disclosure, documentation and labeling
- ✚ ISO 7176-16 1997 : Resistance to ignition of upholstered parts- Requirements and test methods
- ✚ ISO 7176-21 2003 : Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and motorized scooters

Signature

Signature



Position

Marketing  
Director

Date

2014.12.03

The following European Authorized Representative is stated to the declaration:

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