HEARTWAY MEDICAL PRODUCTS CO.,LTD.

Declaration of Conformity

This European Declaration of Conformity is issued under the sole responsibility of the manufacturer.

Name of Company	Address	SRN
Heartway Medical Products Co., Ltd	NO.18 Jingke Central 1st Rd., Nantun Dist., Taichung City 40852,Taiwan(R.O.C.)	TW-MF-000003315

Name of Company	Address	SRN	Phone/email
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	NL-AR-000000116	+31.70.345.8570 EmergoEurope@ul.com

Product Name	Code / Catalog Number	Basic UDI-DI
Power Scooter	S19/S19+/S19V/S26/S12/S21F/S16	471987123PSYV
Intended Purpose	**Photo**	
Moving of disabled persons by self-driving	N/A	

Device Classification		Common Specifications / Standards
Class:	I	Directive 2011/65/EU Directive 2012/19/EU Directive 2006/42/EC EN 12184:2014 Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods EN ISO 13485: 2016 Medical devices - Quality management systems - Requirements for regulatory purposes. EN ISO 14971:2019 Medical devices -- Application of risk management to medical devices. EN ISO 15223-1:2016 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements. EN 62366:2008 Medical devices. Application of usability engineering to medical devices
Rule:	13	

		ISO 7176-1 :2014 Wheelchairs -- Part 1: Determination of static stability. ISO 7176-2 : 2001 Wheelchairs -- Part 2: Determination of dynamic stability of electric wheelchairs. ISO 7176-3 : 2012 Wheelchairs -- Part 3: Determination of effectiveness of brakes. ISO 7176-4 : 2008 Wheelchairs -- Part 4: Energy consumption of electric wheelchairs and scooters for determination of theoretical distance range. ISO 7176-5 : 2008 Wheelchairs -- Part 5: Determination of dimensions, mass and maneuvering space. ISO 7176-6 : 2001 Wheelchairs -- Part 6: Determination of maximum speed, acceleration and deceleration of electric wheelchairs. ISO 7176-7 : 1998 Wheelchairs -- Part 7: Measurement of seating and wheel dimensions. ISO 7176-8 : 2014 Wheelchairs -- Part 8: Requirements and test methods for static, impact and fatigue strengths. ISO 7176-9 : 2009 Wheelchairs -- Part 9: Climatic tests for electric wheelchairs. ISO 7176-10 : 2008 Wheelchairs -- Part 10: Determination of obstacle-climbing ability of electrically powered wheelchairs. ISO 7176-11 : 2012 Wheelchairs -- Part 11: Test dummies. ISO 7176-13 : 1989 Wheelchairs -- Part 13: Determination of coefficient of friction of test surfaces. ISO 7176-14 : 2008 Wheelchairs -- Part 14: Power and control systems for electrically powered wheelchairs and scooters -- Requirements and test methods. ISO 7176-15 : 1996 Wheelchairs -- Part 15: Requirements for information disclosure, documentation and labelling. ISO 7176-16 : 2012 Wheelchairs -- Part 16: Resistance to ignition of postural support devices. ISO 7176-21 : 2009 Wheelchairs -- Part 21: Requirements and test methods for electromagnetic compatibility of electrically powered wheelchairs and scooters, and battery chargers. ISO 10993-1:2018 Biological evaluation of medical devices: Part 1:Evaluation and testing EN ISO 10993-5:2009 Biological evaluation of medical devices -- Part 5: Tests for in vitro cytotoxicity ISO 10993-10:2010 Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization IEC 60601-1-6:2010 + A1:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

		IEC 62304:2006 +A1:2015 Medical device – software life cycle processes.

Heartway Medical Products declares that the above-mentioned products meet the provision of the following EU legislation:

- Medical Devices Regulation (EU) 2017/745
- Restriction of the use of certain hazardous substances (RoHS) Directive 2011/65/EU
- Machinery Directive 2006/42/EC
- Waste Electrical and Electronic Equipment (WEEE) Directive 2012/19/EU

COMPANY REPRESENTATIVE: David Wu

TITLE: Quality Management Representative **SIGNATURE:**

PLACE: Taiwan **DATE:** 27.Oct.2021