

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

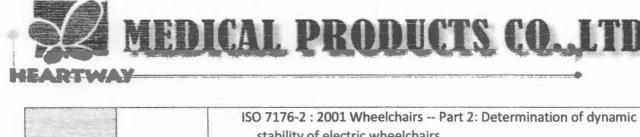
Name of Company	Address	SRN	Phone/email
Emergo Europe	Prinsessegracht 20	NL-AR-000000116	+31.70.345.8570
	2514 AP The Hague		EmergoEurope@ul.com
	The Netherlands		

Product Name	Code / Catalog Number	Basic UDI-DI
Power Wheelchair	N/A	471987123PWZ5
Intended Purpose	Photo	-
This medical equipment is intended to provide mobility to persons restricted to a seated position, e.g. for patient recovery, especially for the leg disabled person.	N/A	

Device Classifica	tion	Common Specifications / Standards
Class:	1	Directive 2011/65/EU
Rule:	13	 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 ISO 7176-1 :2014 Wheelchairs Part 1: Determination of static stability.

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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.

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

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- 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: Thomas Ho

TITLE: Managing director

SIGNATURE:

PLACE: Taiwan

DATE: 14.Oct.2021

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