



Jerry<sup>®</sup>medical  
吉芮医疗

JERRY MEDICAL INSTRUMENT (SHANGHAI) CO., LTD

Tel: +86 21 59517539 Fax: +86 21 59517626

Building 12, #615 Fengdeng Rd, Malu Town, Jiading District, Shanghai, China

## *EC Declaration of Conformity*

**Manufacturer: Jerry Medical Instrument (Shanghai) Co., Ltd**  
**# 615 Fengdeng Rd, Malu Town, Jiading District, Shanghai, China**

According to the EC Declaration of Conformity set out according to Annex V, section 3 of the Directive 93/42/EEC on Medical Devices, for the following products Series:

<u>Item No.</u>	<u>Product name:</u>
1. JRWD 301	Electric wheelchair
2. JRWD 302	Electric wheelchair
3. JRWD 501	Electric wheelchair
4. JRWD 601	Electric wheelchair
5. JRWD 602	Electric wheelchair
6. JRWD 1001	Electric wheelchair
6. JRWD 1002	Electric wheelchair
7. JRWD 1801	Electric wheelchair

**Effectively: For all products manufactured after date of August 1st, 2015.**





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And declare that:

- The product meets the essential requirements set out in MDD 93/42/EEC, Annex I.
- The above products comply with the assessment criteria of the Council Directive 93/42/EEC, Medical Device Directive, Annex VII.

<u>Standard</u>	<u>Title</u>	<u>Year</u>
EN 12182	Technical aids for disabled persons – General requirements and test methods.	1999
EN 1441	Risk assessment for medical devices	1998
EN 14971	Medical Devices. Application of risk Management to medical devices	2000
EN 1041	Information supplied by the manufacturer with medical devices.	1998
EN 980	Graphical symbols for use in the labeling of medical devices.	2003
IEC 60601-1:	Medical Electrical Equipment. General Requirements for safety and essential performance + A1:2012	2005
IEC 60601-1-2	Medical Electrical Equipment General Requirements for basic safety and essential performance-collateral standard: Electromagnetic Compatibility-Requirements and Tests	2007
ISO 7176-21	Power wheelchairs and electric scooter and their chargers	2000
	Requirements and tests methods of electromagnetic compatibility	
EN 12184	Power wheelchair, electric scooter and their chargers --Requirements and test methods	2009
	Classification: 93/42/EEC MDD, Annex IX: Class I	
	The manufacturing site for the above products complies with:	
EN ISO 13485	Medical devices – Quality management systems Requirements for regulatory purposes (ISO13485:2003).	2003

# 615 Fengdeng Rd, Malu Town, Jiading District, Shanghai, China



*Chen Jian Guo*  
General Manager

August 1st, 2015

