



Jerry medical
吉芮医疗

JERRY MEDICAL INSTRUMENT (SHANGHAI) CO., LTD

Tel: +86 21 59517539

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Block B, Building 12, No. 615 Fengdeng Rd., Malu Town, Jiading District, Shanghai, China

EC Declaration of Conformity

Manufacturer: Jerry Medical Instrument (Shanghai) Co., Ltd

Building 12, No. 615 Fengdeng Rd., Malu Town, Jiading District, Shanghai, China

European Authorized Representative:

Name: Luxus Lebenswelt GmbH

Add: Kochstr. 1, 47877, Willich, Germany

DIMDI Code: DE/0000047791

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:

Product name: POWER WHEELCHAIR / ELECTRIC WHEELCHAIR

Model No.: JRWD301, JRWD301X, JRWD301P, JRWD301LP, JRWD302, JRWD302X, JRWD303, JRWD303X, JRWD1002, JRWD1002X, JRWD1003, JRWD1801, JRWD1801X, JRWD1801L, JRWD1802, JRWD1803, JRWD501, JRWD502, JRWD503, JRWD601, JRWD602, JRWD603, JRWD6010, JRWD6012, JRND701

Effectively: For all products manufactured after date of Jan. 1st, 2020.

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.

Standard	Title	Year
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



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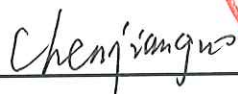
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IEC	Medical Electrical Equipment	2007
60601-1-2	General Requirements for basic safety and essential performance-collateral standard: Electromagnetic Compatibility-Requirements and Tests	
ISO 7176-21	Electric wheelchairs and their chargers	2000
	Requirements and tests methods of electromagnetic compatibility	
EN 12184	Electric wheelchair and their chargers	2009
	--Requirements and test methods	
	Classification: 93/42/EEC MDD, Annex IX: Class I	
	The manufacturing site for the above products complies with:	
EN ISO13485	Medical devices – Quality management systems	2016
	Requirements for regulatory purposes (ISO13485:2003).	
Validity period: 2 years.		

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General Manager

Jan. 1st, 2020

