EU Declaration of Conformity

Manufacturer:	Jerry Medical Instrument (Shanghai) Co.,Ltd Address:No.615 Fengdeng Industrial Zone, Malu Town, Jiading District,Shanghai,China
SRN:	CN-MF-000007638
European Representative:	MedPath GmbH Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany
SRN:	DE-AR-000000087
Product Name:	Electric Wheelchair
Models:	JRWD501, JRWD502, JRWD503, JRWD601, JRWD602,JRWD603, JRWD6010, JRWD6012
GMDN Code:	40840
UMDN Code:	16-214
UDI-DI:	69343741002615H

Classification (MDR, Annex VIII): Class I, Rule 13.

Conformity Assessment Route: EU DECLARATION OF CONFORMITY following the Annex II + Annex III + Article 19 of MDR (EU) 2017/745.

We herewith under our sole responsibility declare that the above mentioned products meet the transposition into national law, the provisions of the following EU Regulation and Standards. All supporting documentations are retained under the premises of the manufacturer.

The manufacturer is exclusively responsible for the declaration of conformity.

General applicable regulations, directives:
Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.

Applied standards, common specification, guidance:
EN 12184:2014, EN ISO 15223-1:2016, EN 1041:2008+A1:2013, EN ISO 14971:2012, EN 62366-1:2015+AC:2015, ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2010, EN 60601-1:2006/A1:2013, EN 60601-1-2:2015, EN 60601-1-6:2010+A1:2015, EN 62304:2006+A1:2015.

Signature: Chen jian guo

Name:

Position: General Manager

Place/date: Shanghai City, Dec.1st, 2020

JERRY MEDICAL INSTRUMENT (SHANGHAI) CO.,LTD. 杰瑞医疗器械(上海)有限公司

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