DECLARATION OF CONFORMITY

TO REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices

Manufacturer:
Name: JiangSu YuYue Medical Equipment & Supply CO., LTD.
Address: No.1 Baisheng Road Development Zone, 212300 Danyang, Jiangsu, CHINA.
SRN: CN-MF-000012834

European Representative:
Name: Metrax GmbH
Address: Rheinwaldstr. 22, D-78628 Rottweil, Germany
SRN: DE-AR-000005481

Product Name: ELECTRIC WHEELCHAIR
Model: D130EL
BASIC UDI-DI: 693325791648JP

Classification (Annex VIII): I
Conformity Assessment Route: Class I: EC conformity declaration according to annex II+ annex III

The object of the declaration described above is in conformity with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

We herewith declare under our sole responsibility that the above mentioned products meet Medical Device Regulation: Regulation (EU) 2017/745. All supporting documentations are retained under the premises of the manufacturer.

Medical Device Regulation: Regulation (EU) 2017/745

STANDARDS APPLIED: SEE ATTACHED LIST OF (HARMONISED - EN) STANDARDS FOR WHICH DOCUMENTED EVIDENCE OF COMPLIANCE CAN BE PROVIDED.

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JIANGSU YUYUE MEDICAL EQUIPMENT & SUPPLY CO.,LTD
江苏鱼跃医疗设备股份有限公司

Registration No.: DE/CA39/1373/48
Start of CE Marking: Date CE mark was affixed: 2021.4.14
Place, Date of Issue: DanYang, JiangSu , P.R.CHINA 2022-03-18
Name: Bill Wang(Director of quality)

S/N	Ref. No.	Title
1	Regulation (EU) 2017/745	Medical Device Regulation
2	MEDDEV 2 12-1 Rev:8	Vigilance report form for field safety corrective action report Form Manufacturer's Field Safety Corrective Action Report
3	MEDDEV.2.7.1 Rev.4	Clinical evaluation: A guide for manufacturers and notified bodies
4	EN ISO 14971:2012	Medical Device -Application of Risk Management in Medical Device
5	EN ISO 13485:2016	Medical devices-Quality management systems— Requirements for regulatory purposes
6	EN ISO15223-1:2016	Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied General requirements.
7	EN 1041:2008	Terminology, Symbols and Information Related to Medical Devices –Information Provided by Manufacturers of Medical Devices
8	ISO 10993-1:2018	Biological evaluation of medical devices---part 1: Evaluation and testing
9	EN ISO10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
10	EN ISO10993-10:2013	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
11	EN 12184:2014	Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods
12	ISO 7176-16:2012	Wheelchairs — Part 16: Resistance to ignition of postural support devices
13	EN60601-1: 2012	Medical electrical equipment — Part 1: General requirements for basic safety and essential performance
14	EN60601-1-2:2014	Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests

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