

DECLARATION OF CONFORMITY TO REGULATION (EU) 2017/745 CONCERNING MEDICAL DEVICES

Manufacturer:

Name: JiangsuYuyueMedicalEquipment& SupplyCO., LTD.

Address: Yunyang Industrial Park ,Danyang City ,Jiangsu Province,China. 212300

European Representative:

Name: Metrax GmbH

Address: Rheinwaldstr. 22, D-78628 Rottweil, Germany

Product Name: Electric Wheelchair

Models: D130EL,E130FL

UMDNS Code 16214

Classification: I (Rule 4)

Conformity Assessment Route: MDR Article 19, Annex II+III

We declare the compliance of the above medical device with the applicable requirements of the following standards:

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 ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
10	EN ISO 10993- 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

Place, Date of Issue: Danyang , Jiangsu, P.R.CHINA2020- 12-03

Name: Gumig Jing

Position: Management Representative

