

EC DECLARATION OF CONFORMITY

According to EU Medical Devices Regulation 2017/745

Manufacturer: Shanghai Bangbang Robotics Co., Ltd.
Room 501, Building 3, No.188 Zhongchen Road,
Songjiang District, Shanghai, China

SRN: CN-MF-000028321

European Representative: Kingsmead Service B.V.
Zonnehof 36, 2632 BE, Nootdorp, Netherland

SRN NL-AR-000002066

Product Name: Electric Wheelchair (Robooter E60)

Product Model: BBR-E60-01、BBR-E60-02、BBR-E60-03、BBR-E60-04

Classification: Class I according to Rule 13 of MDR Annex VIII

Basic UDI: 697484214 E60 PT

Applied Standards: EN ISO 13485:2016/A11:2021; EN ISO 15223-1:2021;
EN ISO 14971:2019/A11:2021; ISO 20417:2021 ;
ISO 7176-21:2009; EN 60601-1-2:2015;
EN 12184:2022; EN 60601-1:2006/A1:2013

Conformity assessment procedure: MDR Annex II+III

CE certificate No.: N.A.

Name and ID of the Notified Body: N.A.

We, the manufacturer, herewith declare under our sole responsibility that the above-mentioned products meet the provisions of the EU Medical Devices Regulation 2017/745. All supporting documentations are retained under the premises of the manufacturer.



Signature:

Name/Position: Li Jian Guo/GM

Date: 2023/08/24

Place: Shanghai/ China