



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
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2909VA Capelle aan den IJssel, The
Netherlands
SRN: NL-AR-000000247

Conformity Assessment

Conformity Assessment Procedure
Annex II+III of Regulation (EU) 2017/745

Applicable Standards

EN ISO 14971:2019
EN ISO 15223-1:2021
EN ISO 20417: 2021
EN ISO 10993-1:2020
EN ISO 10993-5:2009
EN ISO 10993-10: 2023
EN ISO 10993-23: 2021
EN 12184:2022
EN 60601-1-2:2015/A1:2021

Remark

The declaration of conformity is valid in connection with the release technical document BBR-CE-TCF-001.

All the supporting documentation is retained at the premises of the manufacturer.

The Declaration of Conformity is exclusively under the sole responsibility of the manufacturer.

Manufacturer

Name: Jiangsu Bangbang Intelligent Technology Co., Ltd.

Address: Building 1, No.2 Hongren Road, Tianning District, Changzhou, Jiangsu, 201300, China

SRN:

Product Information

Name: ELECTRIC WHEELCHAIR

Model : X40, E40,E40s, E40AA1, E60, E80, C40, C60, F20, P60, P80


EMDN: Y122127

Basic UDI-DI: 697824658EW6E

Classification: Class I, According to Rule 13, Annex VIII, Regulation (EU) 2017/745

Declaration

We herewith declare that the above-mentioned products meet the requirements of Medical Device Regulation (EU) 2017/745 and the applicable standards above.

Signature:  Date: 2023/1/22

Position: Management Representative

Place: Jiangsu/China



Annex

Name	Model
ELECTRIC WHEELCHAIR	X40, E40,E40s, E40AA1, E60, E80, C40, C60, F20, P60, P80

