



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Fascinatio Boulevard 522, Unit 1.7,
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 60601-1:2006/A2:2021
EN 60601-1-2:2015/A1:2021
EN 62366-1:2015

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Y122127-01.

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: HEBEI WEBIAN MEDICAL INSTRUMENT TRADING CO., LTD
Address: A1-2703 SHIDAI BUILDING, GUANG AN STREET, CHANG AN DISTRICT, SHIJIAZHUANG CITY, HEBEI PROVINCE, CHINA

SRN: CN-MF-000031958

Product Information

Name: ELECTRIC WHEELCHAIR
Model : LYI-WBECG-1 、 LYI-WBECG-6 、 LYAL-WBECG-1、 LYAL-WBECG-2、 LYAL-WBECG-3、 LYAL-WBECG-4、 LYPS-WBECG-1、 LYPS-WBECG-2、 LYPS-WBECG-3 、 LYPS-WBECG-4 、 LYPS-WBECG-5 、 LYPS-WBECG-6 、 LYPS-WBECG-7 、 LYPS-WBECG-8 、 LYPS-WBECG-9 、 LYPS-WBECG-10 、 LYPS-WBECG-11 、 LYPS-WBECG-12 、 LYPS-WBECG-13、 LYPS-WBEZX-1

EMDN: Y122127

Basic UDI-DI: 697593980EW001QC

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: 2024.5.13

Position: GM Place: Hebei/China

