



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 60601-2-52:2010+A1:2015
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-V080601-02.

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 BED

Model : BCE1-WB03-1 、 BCE2-WB01-1 、 BCE2-WB01-3 、 BCE2-WB02-1、 BCE2-WB02-5、 BCE2-WB03-1、 BCE3-WB01-1、 BCE3-WB01-5、 BCE3-WB02-1、 BCE3-WB02-2、 BCE3-WB02-3、 BCE3-WB02-4、 BCE3-WB02-5、 BCE3-WB02-7、 BCE3-WB03-1、 BCE5-WB02-1、 BCE5-WB02-2、 BCE5-WB02-3、 BCE5-WB02-4、 BCE5-WB02-5、 BCE5-WB02-6、 BCE5-WB02-7、 BCE5-WB02-8、 BCE5-WB02-9 、 BCE5-WB02-10 、 BCE5-WB02-12 、 BCE5-WB02-13、 BCEM-WB05-1

EMDN: V080601

Basic UDI-DI: 697593980EB001KR

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

