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: 2013

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-V08068002-03.

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: Air mattress
Model: M05、M05-1、M05-2 、M01 M01-1 M02 M03 M03-1 M04 M04-1 M04-2 M04-3
EMDN: V08068002
Basic UDI-DI: 697593980AM001LS
Classification: Class I, According to Rule 1, Annex VIII, Regulation (EU) 2017/745

Declaration

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

Signature: Date: 2022.11.08

Position: GM Place:Hebei/China