DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, 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
EN 12184:2014
EN 60601-1:2006+A1:2013+
AC:2014+A12:2014 +A2:2020
EMC EN 60601-1-2:2015+A1:2020

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Y122124-02.

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: NINGBO BAICHEN MEDICAL DEVICES CO., LTD.

Address: Room 903, Diqu Building, 666 Taikang Middle Road, Ningbo, Zhejiang, CN

SRN: CN-MF-000021409

Product Information

Name: SCOOTER

Model: BC-MS305 ; BC-MS306 ; BC-MS307 ; BC-MS308 ; BC-MS309 ; BC-MS310 ; BC-MS3331 ; BC-MS3431 ; BC-MS3458 ; BC-MS3433 ; BC-MS3435 ; BC-MS3459 ; BC-MA211 ; BC-MS001 ; BC-MS018

EMDN: Y122124

GMDN: 45684

Basic UDI-DI: /

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: 2022.04.22

Position: GM

Place: Ningbo/China