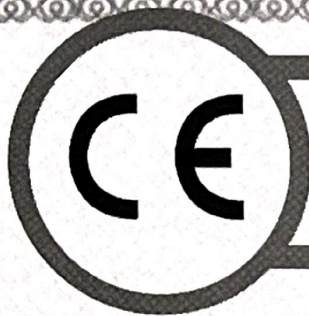




DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

Name: SUNGO Europe B.V.

Address: Fascinatio Boulevard 522, Unit 1.7,
2909VA Capelle aan den IJssel, The Netherlands

SRN: NL-AR-000000247

Manufacturer

Name: Ningbo Baichen Medical Devices Co., Ltd.

Address: Room 2101, Diqu Building, 666
Taikang Middle Road, Ningbo, Zhejiang, CN

SRN: CN-MF-000021409

Conformity Assessment

Conformity Assessment Procedure

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

Applicable Standards

EN ISO 14971: 2019/A11:2021

ISO 15223-1:2021/Amd 1:2025

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

Product Information

Name: Scooter

Model: Refer to Annex

EMDN: Y122124

Basic UDI-DI: 697518562BCMS001QU

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

Remark

*The declaration of conformity is valid in connection with
the release technical document MDR-TCF-002.*

*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.*

File No.: MDR-TCF-002-09

Version: A/1

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: 2025.6.9

Position: GM

Place: Ningbo/China

Annex

Scooter

BC-MS100, BC-MS120, BC-MS130, BC-MS150, BC-MS160, BC-MS180, BC-MSA1, BC-MS308, BC-MS309, BC-MS310, BC-MS320, BC-MS330, BC-MS350, BC-MS360, BC-MS380, BC-MS390, BC-MS210, BC-MS220, BC-MS230, BC-MS250, BC-MS260, BC-MS280, BC-MS290, BC-MS270, BC-MS610, BC-MS620, BC-MS630, BC-MS650, BC-MS660, BC-MS680, BC-MS910, BC-MS920, BC-MS930, BC-MS950, BC-MS960, BC-MS01, BC-MS02, BC-MS03, BC-MS05

