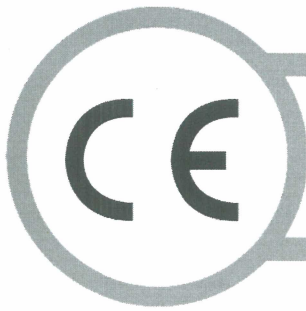




DECLARATION OF CONFORMITY

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
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 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 MDR-TCF-001
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-001-08
Ver: A/0

Manufacturer

Name: Wiseton Industries Limited
Address: No.9 Jiahe Road, Jiashan County, Jiaxing
City, Zhejiang Province, P.R. China
SRN: CN-MF-000040574

Product Information

Name: Electric Nursing Bed
Model: B300/B100
EMDN: V080601
Basic UDI-DI: 697690461ENBUT
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:2025/6/9

Position: GM

Place: Zhejiang /China