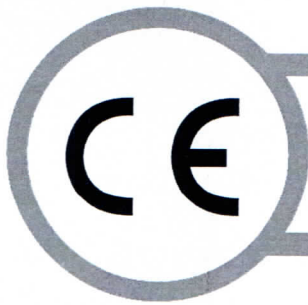




DECLARATION OF CONFORMITY

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 60601-1-2:2015
EN 60601-1:2006+A1:2013+AC:2014
IEC/EN 60601-2-52:2009+A1:2015
EN 60601-1-6:2010+A1:2015

Remark

*The declaration of conformity is valid in connection
with the release technical document CE/MDR-
Z12011202-01.*

*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: 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 Treatment Table

Model: AVANT, CLASSIC

EMDN: Z12011202

Basic UDI-DI: 697690461002N2

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:

OLIVIER
JIANMIN YE

Date:2024.10.10

Position: GM

Place: Zhejiang/China