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-Y1899-02.

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: FAMICA INTERNATIONAL CO. LTD.
Address: 4 F, NO. 23, SEC. 2, ZHONGZHENG E. RD., DANSHUI DIST., NEW TAIPEI CITY 251, TAIWAN
SRN: TW-MF-000034084

Product Information

Name: Toilet Frame
Model: AA41(AAA041-XXX) / AA42(AAA042-XXX)
EMDN: Y091212
Basic UDI: 471988023AAM0016S
Classification: Class I, according to Rule 1, 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: 02, Mar, 2023

Position: VP Place: Taiwan