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

Remark

The declaration of conformity is valid in connection with the release technical document CE/MDR-Y1203-08.

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: Zhongshan A&J Medical Equipment Co., Ltd.
Address: 3 Shenghui South Road, Nantou Town, Zhongshan City, Guangdong, 528427 China.
SRN: CN-MF-000038649

Product Information

Name: Crutch
Model: 131
EMDN: Y1203
Basic UDI-DI: / 697786346CrutchVK
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.

ZHONGSHAN A&J MEDICAL EQUIPMENT CO.,LTD 中山荣杰医疗器材工业有限公司

Signature: Date: 2023.8.30

Position: GM Place: Guangdong /China