



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

SUNGO Europe B.V.
Olympisch Stadion 24, 1076DE
Amsterdam, 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: 2016
EN 1041:2008+A1:2013
ISO 10993-1: 2018
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-KAFO -03.

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: Hengshui Gangsheng Medical Instruments Co., Ltd.

Address: (1000 meters South of Dadi Town Government) Dadi Village, Dadi town, Shenzhou City, Hengshui City, Hebei Province, China

Product Information

Name: Lower Limbs brace

Model: GS516、GS554、GS567、GS588、GS5012、GS5016、GS5036、GS5050、GS5111、GS5112、GS5118、GS5201; GS603、GS606、GS625、GS644、GS655、GS6007、GS6019、GS6085、GS6086、GS6098、GS6115B、GS6119、GS5134、GS5117、GS644 Or customized

GMDN: 41070

Basic UDI-DI: /

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: 2021. 7. 15

Position: GM Place: Hebei/China

