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 ISO 20417: 2021
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-HSM-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: ZHANGJIAGANGTENGDA MACHINERY MANUFACTURER CO.,LTD
Address: NO.999 Hongqi Road, Changyinsha Modern Agricultural Demonstration Area, Zhangjiagang city, Jiangsu 215623, China

Product Information

Name : Emergency Stretcher
Model : See Annex
GMDN : See Annex
UDI-DI:069748666609996
Basic UDI-DI : 697486666stretcher999SE
SRN : CN-MF-000013468
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: 2021.9.28

Position: GM Place: Zhangjiagang/China

Annex

Product Name	Model	GMDN	Basic UDI-DI
Emergency Stretcher	MLF999-C1,MLF999-C2,MLF999-C3, MLF999-C, MLF999-CA, MLF999-B, MLF999-B1, MLF999-A3-1,MLF999-A3-2, MLF999-A3-3, MLF999-F1, MLF999-F2, MLF999E , TD010161,TD010163 MLF999-E1,MLF999-A,MLF999-D,TD+1	35892, 35843, 16906, 13818	697486666stretcher999SE

ZHANGJIAGANG TENGDA MACHINERY MANUFACTURER CO.,LTD.
张家港市腾达机械制造有限公司
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