



DECLARATION OF CONFORMITY

ACCORDING TO (EU) 2017/745 MEDICAL DEVICE REGULATION

EU Representative

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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: 2023. 3.16

Position: GM Place: Zhangjiagang/China



Annex

Product Name	Model		GMDN	Basic UDI-DI
Emergency Stretcher	MLF999-C1	TD010131A	TD010131E	35892, 35843, 16906, 13818 697486666stretcher999SE
		TD010131B	TD010131F	
		TD010131C	TD010131G	
		TD010131D	TD010131H	
	MLF999-C2	TD010132	TD010132A	
		TD010132B		
	MLF999-C3	TD+4	TD01081B	
	MLF999-C	TD01013A	TD01013B	
		TD01013C	TD01013D	
		TD01013E	TD01013F	
	MLF999-CA	TD010133A	TD010133C	
		TD010133D		
	MLF999-B	TD01012A	TD01012B	
		TD01012C		
	MLF999-B1	TD010121		
	MLF999-A3-1	TD010114A	TD010114B	
		TD010114C	TD010114D	
	MLF999-A3-3	TD010114E-A	TD010114E-B	
	MLF999-A3-2	TD010113A	TD010113B	
	MLF999-F1	TD+8A		
	MLF999-F1	TD+8B		
	MLF999E	TD01016	TD01016A	
	TD010161	TD010163		
	MLF999-E1	TD010162A	TD010162B	
		TD010162C		
	MLF999-A	TD01010	TD01011	
TD010111		TD010112		
TD010115		TD010116		
TD010117				
MLF999-D	TD01015	TD010151		
	TD010152	TD010153		
	TD010154	TD010155		
	TD010156	TD010157		
TD+1				

MANUFACTURER CO., LTD.

