



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: 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-HSM-01.

All the supporting documentation is retained at the promises 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
SRN: CN-MF-000013468

Product Information

NAME: EMERGENCY STRETCHER

MODEL: SEE ANNEX

GMDN: SEE ANNEX

UDI-DI: 069748666609996

BASIC UDI-DI: 697486666STRETCHER999SE

CLASSIFICATION: CLASS I, ACCORDING TO RULE 1,
ANNEX VII, 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: 2024. 6. 27

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				

