


DECLARATION OF CONFORMITY				
Product Name: LeggyFix		Product no.: 0915	Product version: 54	
APPROVED BY TYTEX		APPROVED BY CUSTOMER	VALID FROM 30. April 2021	VERSION NO. 1.2

DECLARATION OF CONFORMITY

According to Regulation 2017/745 on Medical Devices (MDR), Tytex A/S hereby declares to fulfil all relevant requirements for the below mention products as set out in Annex I General safety and performance requirements, Annex II Technical documentation, Annex III Technical documentation on post-market surveillance and Annex XIV Clinical evaluation and post-market follow-up.

LeggyFix are class 1, rule 1; non-sterile CE marked products with intended use as textile fixation device for fixation of a urine bag on a body part or limb of a human being.

SRN: DK-MF-000003620

Brand: CareFix

Product number	Product name	Size	Colour	Basic UDI-DI
0915 54-01	LeggyFix	X- Small	White	57039361265120AAGX
0915 54-02	LeggyFix	Small	White	57039361265120AAGX
0915 54-03	LeggyFix	Medium	White	57039361265120AAGX
0915 54-05	LeggyFix	Large	White	57039361265120AAGX
0915 54-07	LeggyFix	X-Large	White	57039361265120AAGX

This declaration is issued under the sole responsibility of Tytex A/S



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