


<b>DECLARATION OF CONFORMITY</b>			
<b>Product Name:</b> LeggyFix		<b>Product no.:</b> 0915	<b>Product version:</b> 54
APPROVED BY TYTEX		APPROVED BY CUSTOMER	VALID FROM 28. November 2019
		VERSION NO. 1.0	

**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.

<b>Brand</b>	<b>Product name</b>	<b>Product No.</b>	<b>Size</b>
Carefix	LeggyFix	0915	S, M, L, XL

**Basic UDI-DI:**

Product number	GTIN inner	GTIN outer
0915 54-01.01.Y77	57 03936 005570	57 03936 005525
0915 54-02.01.Y77	57 03936 005587	57 03936 005532
0915 54-03.01.Y77	57 03936 005594	57 03936 005549
0915 54-05.01.680	57 03936 005600	57 03936 005556

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



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