



## Declaration of identical construction of medical devices

This is to confirm to

**Sarstedt AG & Co. KG**

I hereby declare that the below list of products are identical in construction, fit and function

Tytex		Sarstedt	
Product number	Product name	Product number	Product name
091554-01.01.672	LeggyFix	74.5767.001	UroStretch Beinbeutel-Befestigung - Small
091554-03.01.672	LeggyFix	74.5767.002	UroStretch Beinbeutel-Befestigung - Medium
091554-05.01.673	LeggyFix	74.5767.003	UroStretch Beinbeutel-Befestigung - Large
091554-07.01.673	LeggyFix	74.5767.004	UroStretch Beinbeutel-Befestigung - X-Large

except for following differences

March 2<sup>nd</sup> 2021


Kim Remin Ankjaer  
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**DECLARATION OF CONFORMITY**

<b>Product Name:</b> LeggyFix		<b>Product no.:</b> 0915	<b>Product version:</b> 54
<b>APPROVED BY</b> TYTEX		<b>APPROVED BY</b> CUSTOMER	<b>VALID FROM</b> 02. March 2020
		<b>VERSION NO.</b> 1.1	

**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	XS, S, M, L, XL

Tytex have accepted that customer Sarstedt AG & Co. KG may label the Carefix LeggyFix with own brand and name – UroStretch Beinbeutel - Befestigung.

**Basic UDI-DI:** 57039361265120AAGX

Tytex				Sarstedt	
Product number	Product name	Size	Colour	Product number	Product name
091554-01.01.672	LeggyFix	S	White	74.5767.001	UroStretch Beinbeutel-Befestigung - Small
091554-03.01.672	LeggyFix	M	White	74.5767.002	UroStretch Beinbeutel-Befestigung - Medium
091554-05.01.673	LeggyFix	L	White	74.5767.003	UroStretch Beinbeutel-Befestigung - Large
091554-07.01.673	LeggyFix	XL	White	74.5767.004	UroStretch Beinbeutel-Befestigung - X-Large

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



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