


**DECLARATION OF CONFORMITY**

<b>Product Name:</b> Post-Op Bra, Lisa		<b>Product no.:</b> 3471	
<b>APPROVED BY</b> TYTEX		<b>APPROVED BY</b> CUSTOMER	<b>VALID FROM</b> 04. May 2021
		<b>VERSION NO.</b> 1.1	

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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.


The Post-Op Bra, Lisa are class I, rule I, non-sterile CE marked products intended for fixation of a bandage or another medical device for post-surgical use and for comfortable wear for a maximum of wound and scar protection.

SRN: DK-MF-000003620

Brand: CareFix

Product number	Product name	Size	Cup size	Colour	Basic UDI-DI
3471 54-01	Post-Op Bra, Lisa	S	AA-B	White	57039361265170ACJ6
3471 54-03	Post-Op Bra, Lisa	M	AA-B	White	57039361265170ACJ6
3471 54-05	Post-Op Bra, Lisa	L	AA-B	White	57039361265170ACJ6
3471 54-07	Post-Op Bra, Lisa	XL	AA-B	White	57039361265170ACJ6
3471 54-09	Post-Op Bra, Lisa	2XL	AA-B	White	57039361265170ACJ6
3471 54-11	Post-Op Bra, Lisa	3XL	AA-B	White	57039361265170ACJ6
3471 55-01	Post-Op Bra, Lisa	S	AA-B	Black	57039361265170ACJ6
3471 55-03	Post-Op Bra, Lisa	M	AA-B	Black	57039361265170ACJ6
3471 55-05	Post-Op Bra, Lisa	L	AA-B	Black	57039361265170ACJ6
3471 55-07	Post-Op Bra, Lisa	XL	AA-B	Black	57039361265170ACJ6
3471 55-09	Post-Op Bra, Lisa	2XL	AA-B	Black	57039361265170ACJ6
3471 55-11	Post-Op Bra, Lisa	3XL	AA-B	Black	57039361265170ACJ6
3471 58-01	Post-Op Bra, Lisa	S	AA-B	White	57039361265170ACJ6
3471 58-03	Post-Op Bra, Lisa	M	AA-B	White	57039361265170ACJ6
3471 58-05	Post-Op Bra, Lisa	L	AA-B	White	57039361265170ACJ6
3471 58-07	Post-Op Bra, Lisa	XL	AA-B	White	57039361265170ACJ6
3471 58-09	Post-Op Bra, Lisa	2XL	AA-B	White	57039361265170ACJ6
3471 58-11	Post-Op Bra, Lisa	3XL	AA-B	White	57039361265170ACJ6

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Product number	Product name	Size	Cup size	Colour	Basic UDI-DI
3471 56-01	Post-Op Bra, Lisa	S	C-E	White	57039361265170ACJ6
3471 56-03	Post-Op Bra, Lisa	M	C-E	White	57039361265170ACJ6
3471 56-05	Post-Op Bra, Lisa	L	C-E	White	57039361265170ACJ6
3471 56-07	Post-Op Bra, Lisa	XL	C-E	White	57039361265170ACJ6
3471 56-09	Post-Op Bra, Lisa	2XL	C-E	White	57039361265170ACJ6
3471 56-11	Post-Op Bra, Lisa	3XL	C-E	White	57039361265170ACJ6
3471 57-01	Post-Op Bra, Lisa	S	C-E	Black	57039361265170ACJ6
3471 57-03	Post-Op Bra, Lisa	M	C-E	Black	57039361265170ACJ6
3471 57-05	Post-Op Bra, Lisa	L	C-E	Black	57039361265170ACJ6
3471 57-07	Post-Op Bra, Lisa	XL	C-E	Black	57039361265170ACJ6
3471 57-09	Post-Op Bra, Lisa	2XL	C-E	Black	57039361265170ACJ6
3471 57-11	Post-Op Bra, Lisa	3XL	C-E	Black	57039361265170ACJ6

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



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