


**DECLARATION OF CONFORMITY**

<b>Product Name:</b> Post-Op Bra, Sophia		<b>Product no.:</b> 3342	
<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, Sophia 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	Colour	Basic UDI-DI
3342 60-01	Post-Op Bra, Sophia	S	White	57039361265170ACJ6
3342 60-03	Post-Op Bra, Sophia	M	White	57039361265170ACJ6
3342 60-05	Post-Op Bra, Sophia	L	White	57039361265170ACJ6
3342 60-07	Post-Op Bra, Sophia	XL	White	57039361265170ACJ6
3342 60-09	Post-Op Bra, Sophia	2XL	White	57039361265170ACJ6
3342 60-11	Post-Op Bra, Sophia	3XL	White	57039361265170ACJ6
3342 61-01	Post-Op Bra, Sophia	S	Black	57039361265170ACJ6
3342 61-03	Post-Op Bra, Sophia	M	Black	57039361265170ACJ6
3342 61-05	Post-Op Bra, Sophia	L	Black	57039361265170ACJ6
3342 61-07	Post-Op Bra, Sophia	XL	Black	57039361265170ACJ6
3342 61-09	Post-Op Bra, Sophia	2XL	Black	57039361265170ACJ6
3342 61-11	Post-Op Bra, Sophia	3XL	Black	57039361265170ACJ6

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



Kim Remin Ankjaer  
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