DECLARATION OF CONFORMITY			
Product Name: Post-Op Bra, Anna		**Product no.:** 3270	
APPROVED BY TYTEX	APPROVED BY CUSTOMER	VALID FROM 04. May 2021	VERSION NO. 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.

The Post-Op Bra, Anna 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
3270 60-01	Post-Op Bra, Anna	S	White	57039361265170ACJ6
3270 60-03	Post-Op Bra, Anna	M	White	57039361265170ACJ6
3270 60-05	Post-Op Bra, Anna	L	White	57039361265170ACJ6
3270 60-07	Post-Op Bra, Anna	XL	White	57039361265170ACJ6
3270 60-09	Post-Op Bra, Anna	2XL	White	57039361265170ACJ6
3270 61-01	Post-Op Bra, Anna	S	Black	57039361265170ACJ6
3270 61-03	Post-Op Bra, Anna	M	Black	57039361265170ACJ6
3270 61-05	Post-Op Bra, Anna	L	Black	57039361265170ACJ6
3270 61-07	Post-Op Bra, Anna	XL	Black	57039361265170ACJ6
3270 61-09	Post-Op Bra, Anna	2XL	Black	57039361265170ACJ6
3270 62-01	Post-Op Bra, Anna	S	Tan	57039361265170ACJ6
3270 62-03	Post-Op Bra, Anna	M	Tan	57039361265170ACJ6
3270 62-05	Post-Op Bra, Anna	L	Tan	57039361265170ACJ6
3270 62-07	Post-Op Bra, Anna	XL	Tan	57039361265170ACJ6
3270 62-09	Post-Op Bra, Anna	2XL	Tan	57039361265170ACJ6

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

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