


DECLARATION OF CONFORMITY

Product Name: Comfort Bra, Celia		Product no.: 5006	
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 Comfort Bra, Celia 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
5006 52-01	Comfort Bra, Celia	S	White	57039361265170ADJ8
5006 52-03	Comfort Bra, Celia	M	White	57039361265170ADJ8
5006 52-05	Comfort Bra, Celia	L	White	57039361265170ADJ8
5006 52-07	Comfort Bra, Celia	XL	White	57039361265170ADJ8
5006 52-09	Comfort Bra, Celia	2XL	White	57039361265170ADJ8

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



Kim Remin Ankjaer
VP of Quality & Environment
Legal Representative