


DECLARATION OF CONFORMITY

Product Name: Panty		Product no.: 0711	
APPROVED BY TYTEX		APPROVED BY CUSTOMER	VALID FROM 30. April 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.

Contenance pants Panty are class 1, rule 1; non-sterile CE marked products with intended use as textile fixation device for fixation of, i.e. a bandage or a pad, worn as normal underwear pants for alleviation of continence diseases or handicap.

SRN: DK-MF-000003620

Product number	Product name	Size	Colour	Basic UDI-DI
0711 50-01	Panty	S	White	57039361105110AACX
0711 50-03	Panty	M	White	57039361105110AACX
0711 50-05	Panty	L	White	57039361105110AACX
0711 50-07	Panty	XL	White	57039361105110AACX
0711 50-09	Panty	2XL	White	57039361105110AACX
0711 50-11	Panty	3XL	White	57039361105110AACX
0711 54-09	Panty	2XL	White	57039361105110AACX

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



Kim Remin Ankjaer
VP of Quality & Environment
Legal Representative



MAKING HEALTHCARE MORE HUMAN
Tytex A/S Tel. +45 9660 4200
Industrivej 21 Fax +45 9660 4201
DK-7430 Ikast info@tytex.dk

Tytex A/S
Industrivej 21
7430 Ikast
Denmark
www.tytex.com
+45 9660 4200