

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.

Continence 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.


Brand	Product name	Product No.	Size
-	Panty	0711	S – 3XL

SRN: DK-MF-000003620

Tytex have accepted that customer Igefa Group may label the Tytex Continence pants Panty with own brand and name

Basic UDI-DI: 57039361105110AACX

Tytex				Igefa Group	
Product number	Product name	Size	Colour	Product number	Product name
0711 50-03.01.V91	Panty	M	White	2133650	Kolibri Comfix Ultra
0711 50-05.01.V91	Panty	L	White	2133652	Kolibri Comfix Ultra
0711 50-07.01.V91	Panty	XL	White	2133654	Kolibri Comfix Ultra
0711 50-09.01.V91	Panty	2XL	White	2133656	Kolibri Comfix Ultra
0711 50-11.01.V91	Panty	3XL	White	2133658	Kolibri Comfix Ultra
0711 50-03.01.V92	Panty	M	White	2133651	Kolibri Comfix Ultra
0711 50-05.01.V92	Panty	L	White	2133653	Kolibri Comfix Ultra
0711 50-07.01.V92	Panty	XL	White	2133655	Kolibri Comfix Ultra
0711 50-09.01.V92	Panty	2XL	White	2133657	Kolibri Comfix Ultra
0711 50-11.01.V92	Panty	3XL	White	2133659	Kolibri Comfix Ultra

DECLARATION OF CONFORMITY			
Product Name: Panty		Product no.: 0711	
APPROVED BY TYTEX		APPROVED BY CUSTOMER	VALID FROM 30. April 2021
		VERSION NO.	1.1

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



Kim Remin Ankjaer
 VP of Quality & Environment
 Legal Representative

TYTEX
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