


DECLARATION OF CONFORMITY			
Product Name: Pretty Soft		Product no.: 3234	
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 Pretty Soft 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
-	Pretty Soft	3234	S – 5XL

SRN: DK-MF-000003620

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

Basic UDI-DI: 57039361105110BAD2

Tytex				Igefa Group	
Product number	Product name	Size	Colour	Product number	Product name
3234 74-01.01.Q19	Pretty Soft	S	White	2097210	Kolibri Comfix Supra
3234 74-03.01.Q19	Pretty Soft	M	White	2097212	Kolibri Comfix Supra
3234 74-05.01.Q19	Pretty Soft	L	White	2097214	Kolibri Comfix Supra
3234 74-07.01.Q20	Pretty Soft	XL	White	2097216	Kolibri Comfix Supra
3234 74-09.01.Q20	Pretty Soft	2XL	White	2097218	Kolibri Comfix Supra
3234 74-11.01.Q21	Pretty Soft	3XL	White	2097220	Kolibri Comfix Supra
3234 74-15.01.Y79	Pretty Soft	4XL	White	2134051	Kolibri Comfix Supra

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



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