

DECLARATION OF CONFORMITY			
Product Name: Soft Support		Product no.: 3246	
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 Soft Support 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
-	Soft Support	3246	S – 3XL


SRN: DK-MF-000003620

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

Basic UDI-DI: 57039361105110BAD2

Tytex				Igefa Group	
Product number	Product name	Size	Colour	Product number	Product name
3246 50-01.01.V93	Soft Support	S	White	2133660	Kolibri Comfix Special
3246 50-03.01.V93	Soft Support	M	White	2133661	Kolibri Comfix Special
3246 50-05.01.V93	Soft Support	L	White	2133662	Kolibri Comfix Special
3246 50-07.01.V93	Soft Support	XL	White	2133663	Kolibri Comfix Special
3246 50-09.01.V93	Soft Support	2XL	White	2133664	Kolibri Comfix Special

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



Kim Remin Ankjaer
VP of Quality & Environment
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TYTEX

MAKING HEALTHCARE MORE HUMAN

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