DECLARATION OF CONFORMITY			
Product Name: Ultra Light		**Product no.:** 6001	
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 Ultra Light 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
-	Ultra Light	3234	S – 2XL

SRN: DK-MF-000003620

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

Basic UDI-DI: 57039361105110BAD2

Tytex				Igefa Group	
Product number	**Product name**	**Size**	**Colour**	**Product number**	**Product name**
6001 50-03.01.V88	Ultra Light	M	White	2133630	Kolibri Comfix Classic
6001 50-05.01.V88	Ultra Light	L	White	2133631	Kolibri Comfix Classic
6001 50-07.01.V88	Ultra Light	XL	White	2133632	Kolibri Comfix Classic

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

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