

## Product Name: Ultra Light APPROVED BY CUSTOMER Product no.: 6001 VALID FROM VERSION NO. 30. April 2021 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	М	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

Ju

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