


| 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



Kim Remin Ankjaer
 VP of Quality & Environment
 Legal Representative

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