

| DECLARATION OF CONFORMITY | | | |
|----------------------------------|------------|--------------------------|------------------------------|
| Product Name: Panty | | Product no.: 0711 | |
| APPROVED BY TYTEX | <i>Jke</i> | 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.

Continance pants Panty 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 |
| - | Panty | 0711 | S – 3XL |

SRN: DK-MF-000003620

Tytex have accepted that customer Igefa Group may label the Tytex Continance pants Panty with own brand and name

Basic UDI-DI: 57039361105110AACX

| Tytex | | | | Igefa Group | |
|-------------------|--------------|------|--------|----------------|----------------------|
| Product number | Product name | Size | Colour | Product number | Product name |
| 0711 50-03.01.V91 | Panty | M | White | 2133650 | Kolibri Comfix Ultra |
| 0711 50-05.01.V91 | Panty | L | White | 2133652 | Kolibri Comfix Ultra |
| 0711 50-07.01.V91 | Panty | XL | White | 2133654 | Kolibri Comfix Ultra |
| 0711 50-09.01.V91 | Panty | 2XL | White | 2133656 | Kolibri Comfix Ultra |
| 0711 50-11.01.V91 | Panty | 3XL | White | 2133658 | Kolibri Comfix Ultra |
| | | | | | |
| 0711 50-03.01.V92 | Panty | M | White | 2133651 | Kolibri Comfix Ultra |
| 0711 50-05.01.V92 | Panty | L | White | 2133653 | Kolibri Comfix Ultra |
| 0711 50-07.01.V92 | Panty | XL | White | 2133655 | Kolibri Comfix Ultra |
| 0711 50-09.01.V92 | Panty | 2XL | White | 2133657 | Kolibri Comfix Ultra |
| 0711 50-11.01.V92 | Panty | 3XL | White | 2133659 | Kolibri Comfix Ultra |

| DECLARATION OF CONFORMITY | | | |
|----------------------------------|---|-----------------------------|-------------------------------------|
| Product Name: Panty | | Product no.: 0711 | |
| APPROVED BY TYTEX |  | APPROVED BY CUSTOMER | VALID FROM 30. April 2021 |
| | | | VERSION NO. 1.1 |

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



Kim Remin Ankjaer
 VP of Quality & Environment
 Legal Representative

TYTEX
MAKING HEALTHCARE MORE HUMAN

Tytex A/S Tel. +45 9660 4200
 Industrivej 21 Fax +45 9660 4201
 DK-7430 Ikast info@tytex.dk

Tytex A/S
 Industrivej 21
 7430 Ikast, Denmark
www.tytex.com
 +45 9660 4200