

# DECLARATION OF CONFORMITY

|                                 |                                |                                    |                            |
|---------------------------------|--------------------------------|------------------------------------|----------------------------|
| <b>Product Name:</b> CarePocket |                                | <b>Product no.:</b> 0912           | <b>Product version:</b> 50 |
| <b>APPROVED BY</b><br>TYTEX     | <b>APPROVED BY</b><br>CUSTOMER | <b>VALID FROM</b><br>23. June 2021 | <b>VERSION NO.</b><br>1.0  |

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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.

CarePocket are class 1, rule 1; non-sterile CE marked products with intended use as textile fixation device for fixation of a urine bag on a body part or limb of a human being.

|              |                     |                    |             |
|--------------|---------------------|--------------------|-------------|
| <b>Brand</b> | <b>Product name</b> | <b>Product No.</b> | <b>Size</b> |
| Carefix      | CarePocket          | 0912               | S, M, L, XL |

SRN: DK-MF-000003620

Tytex have accepted that customer GHC German Health Care GmbH may label the Carefix CarePocket with own brand and name – Fixierstrümpf für Beinbeutel.

**Basic UDI-DI:** 57039361265120AAGX

| Tytex             |              |      |        | GHC German Health Care GmbH |                              |
|-------------------|--------------|------|--------|-----------------------------|------------------------------|
| Product number    | Product name | Size | Colour | Product number              | Product name                 |
| 0912 50-01.01.G51 | CarePocket   | S    | White  | 7126313                     | Fixierstrümpf für Beinbeutel |
| 0912 50-03.01.G51 | CarePocket   | M    | White  | 7126023                     | Fixierstrümpf für Beinbeutel |
| 0912 50-05.01.G52 | CarePocket   | L    | White  | 7126017                     | Fixierstrümpf für Beinbeutel |
| 0912 50-07.01.G52 | CarePocket   | XL   | White  | 12418555                    | Fixierstrümpf für Beinbeutel |

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



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**TYTEX**

MAKING HEALTHCARE MORE HUMAN

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