


**DECLARATION OF CONFORMITY**

|  |   |                                |                                   |
|--|---|--------------------------------|-----------------------------------|
| <b>Product Name:</b> Post-Op Bra, Mary |   | <b>Product no.:</b> 3343       |                                   |
| <b>APPROVED BY</b><br>TYTEX            |  | <b>APPROVED BY</b><br>CUSTOMER | <b>VALID FROM</b><br>04. May 2021 |
|  |   | <b>VERSION NO.</b><br>1.1      |                                   |

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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.


The Post-Op Bra, Mary are class I, rule I, non-sterile CE marked products intended for fixation of a bandage or another medical device for post-surgical use and for comfortable wear for a maximum of wound and scar protection.

SRN: DK-MF-000003620

Brand: CareFix

| Product number | Product name      | Size | Colour | Basic UDI-DI       |
|----------------|-------------------|------|--------|--------------------|
| 3343 60-01     | Post-Op Bra, Mary | S    | White  | 57039361265170AAJ2 |
| 3343 60-03     | Post-Op Bra, Mary | M    | White  | 57039361265170AAJ2 |
| 3343 60-05     | Post-Op Bra, Mary | L    | White  | 57039361265170AAJ2 |
| 3343 60-07     | Post-Op Bra, Mary | XL   | White  | 57039361265170AAJ2 |
| 3343 60-09     | Post-Op Bra, Mary | 2XL  | White  | 57039361265170AAJ2 |
| 3343 60-11     | Post-Op Bra, Mary | 3XL  | White  | 57039361265170AAJ2 |
| 3343 60-13     | Post-Op Bra, Mary | 4XL  | White  | 57039361265170AAJ2 |
|                |                   |      |        |                    |
| 3343 61-01     | Post-Op Bra, Mary | S    | Black  | 57039361265170AAJ2 |
| 3343 61-03     | Post-Op Bra, Mary | M    | Black  | 57039361265170AAJ2 |
| 3343 61-05     | Post-Op Bra, Mary | L    | Black  | 57039361265170AAJ2 |
| 3343 61-07     | Post-Op Bra, Mary | XL   | Black  | 57039361265170AAJ2 |
| 3343 61-09     | Post-Op Bra, Mary | 2XL  | Black  | 57039361265170AAJ2 |
| 3343 61-11     | Post-Op Bra, Mary | 3XL  | Black  | 57039361265170AAJ2 |
| 3343 61-13     | Post-Op Bra, Mary | 4XL  | Black  | 57039361265170AAJ2 |
|                |                   |      |        |                    |
| 3343 62-01     | Post-Op Bra, Mary | S    | Tan    | 57039361265170AAJ2 |
| 3343 62-03     | Post-Op Bra, Mary | M    | Tan    | 57039361265170AAJ2 |
| 3343 62-05     | Post-Op Bra, Mary | L    | Tan    | 57039361265170AAJ2 |
| 3343 62-07     | Post-Op Bra, Mary | XL   | Tan    | 57039361265170AAJ2 |
| 3343 62-09     | Post-Op Bra, Mary | 2XL  | Tan    | 57039361265170AAJ2 |
| 3343 62-11     | Post-Op Bra, Mary | 3XL  | Tan    | 57039361265170AAJ2 |
| 3343 62-13     | Post-Op Bra, Mary | 4XL  | Tan    | 57039361265170AAJ2 |

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|  |   |                                | <b>VERSION NO.</b><br>1.1         |

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

**TYTEX**

MAKING HEALTHCARE MORE HUMAN

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