

DECLARATION OF CONFORMITY

Product Name: Care Short		Product no.: 3022	
APPROVED BY TYTEX		APPROVED BY CUSTOMER	VALID FROM 30. April 2021 VERSION NO. 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.

Continence pants Care Short 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.

SRN: DK-MF-000003620

Product number	Product name	Size	Colour	Basic UDI-DI
3022 53-00	Care Short	XS	White	57039361105110AACX
3022 53-01	Care Short	S	White	57039361105110AACX
3022 53-03	Care Short	M	White	57039361105110AACX
3022 53-05	Care Short	L	White	57039361105110AACX
3022 53-07	Care Short	XL	White	57039361105110AACX

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
 Industrivej 21
 DK-7430 Ikast

Tel. +45 9660 4200
 Fax +45 9660 4201
 info@tytex.dk

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