DECLARATION OF CONFORMITY			
Product Name: New Premium		**Product no.:** 6052	
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 New Premium 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
6052 50-00	New Premium	XS	White	57039361105110BAD2
6052 50-01	New Premium	S	White	57039361105110BAD2
6052 50-03	New Premium	M	White	57039361105110BAD2
6052 50-05	New Premium	L	White	57039361105110BAD2
6052 50-07	New Premium	XL	White	57039361105110BAD2
6052 50-09	New Premium	2XL	White	57039361105110BAD2
6052 50-11	New Premium	3XL	White	57039361105110BAD2

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

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