


DECLARATION OF CONFORMITY

Product Name: Soft Support		Product no.: 3246	
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.

Contenance pants Soft Support 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		Basic UDI-DI
3246 50-01	Soft Support	S		57039361105110BAD2
3246 50-03	Soft Support	M		57039361105110BAD2
3246 50-05	Soft Support	L		57039361105110BAD2
3246 50-07	Soft Support	XL		57039361105110BAD2
3246 50-09	Soft Support	2XL		57039361105110BAD2
3246 50-11	Soft Support	3XL		57039361105110BAD2

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