


DECLARATION OF CONFORMITY

Product Name: CarePocket		Product no.: 0912	Product version: 50
APPROVED BY TYTEX		APPROVED BY CUSTOMER	VALID FROM 06. 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.

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.

Brand	Product name	Product No.	Size
Carefix	CarePocket	0912	S, M, L, XL

Product number	Product name	Size	Colour	Basic UDI-DI
0912 50-01	CarePocket	Small	White	57039361265120AAGX
0912 50-03	CarePocket	Medium	White	57039361265120AAGX
0912 50-05	CarePocket	Large	White	57039361265120AAGX
0912 50-07	CarePocket	X-Large	White	57039361265120AAGX

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



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