DECLARATION OF CONFORMITY			
Product Name: CarePocket		**Product no.:** 0912	**Product version:** 50
APPROVED BY TYTEX	APPROVED BY CUSTOMER N/A	VALID FROM 23. June 2021	VERSION NO. 1.0

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

SRN: DK-MF-000003620

Tytex have accepted that customer GHC German Health Care GmbH may label the Carefix CarePocket with own brand and name – Fixierstrümpf für Beinbeutel.

Basic UDI-DI: 57039361265120AAGX

Tytex				GHC German Health Care GmbH	
Product number	**Product name**	**Size**	**Colour**	**Product number**	**Product name**
0912 50-01.01.G51	CarePocket	S	White	7126313	Fixierstrümpf für Beinbeutel
0912 50-03.01.G51	CarePocket	M	White	7126023	Fixierstrümpf für Beinbeutel
0912 50-05.01.G52	CarePocket	L	White	7126017	Fixierstrümpf für Beinbeutel
0912 50-07.01.G52	CarePocket	XL	White	12418555	Fixierstrümpf für Beinbeutel

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

Rasmus Borgstrøm Henriksen
Medical Project Manager, MGT
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

Heruntergeladen von Gast (IP 216.73.217.10) am 24.11.2026 um 18:14 Uhr · sana.swiss