EU Declaration of Conformity		Product Family: Urology
APROVED BY: TYTEX A/S	VALID FROM: 2026-04-08	VERSION NO.: 1.6

EU Declaration of Conformity

Manufacturers Name:	TYTEX A/S
Manufacturers Address:	MARSVEJ 6, 7430 IKAST, DENMARK
SRN:	DK-MF-000003620
Product Family:	Urology
Brand:	CareFix
Intended purpose:	Fixation of a urine bag on a thigh or calf.
Classification:	Class I, rule I, non-sterile
Conformity assessment route:	TYTEX A/S uses the following procedures for the CE-labeling of their products according the Regulation MDR 2017/745: Class I: EU conformity declaration according to Annex V CE marking of conformity Annex IX Conformity assessment based on a quality management system and assessment of the technical documentation

This declaration of conformity is issued under the sole responsibility of TYTEX A/S. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices.
This declaration is supported by the Quality System approval to ISO 9001 and ISO 13485.
All supporting documentation is retained at the premises of the manufacturer.

Signature:

Ina Nemes
Head of Medical and Regulatory Affairs

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DK-Ikast 2026.04.08:

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Attachment to declaration of conformity UROLOGY

Device number	Device name	Size	Color	Basic UDI-DI
Urine bag fixation				
0902 50-01.01	CarePocket Cotton	S	White	57039361265120AAGX
0902 50-03.01	CarePocket Cotton	M	White	57039361265120AAGX
0902 50-05.01	CarePocket Cotton	L	White	57039361265120AAGX
0902 50-07.01	CarePocket Cotton	XL	White	57039361265120AAGX
0912 50-01.01	CarePocket	S	White	57039361265120AAGX
0912 50-03.01	CarePocket	M	White	57039361265120AAGX
0912 50-05.01	CarePocket	L	White	57039361265120AAGX
0912 50-07.01	CarePocket	XL	White	57039361265120AAGX
0915 54-01.01	LeggyFix	XS	White	57039361265120AAGX
0915 54-02.01	LeggyFix	S	White	57039361265120AAGX
0915 54-03.01	LeggyFix	M	White	57039361265120AAGX
0915 54-05.01	LeggyFix	L	White	57039361265120AAGX
0915 54-07.01	LeggyFix	XL	White	57039361265120AAGX
5080 50-01.01	CarePocket Premium	XS	White	57039361265120AAGX
5080 50-02.01	CarePocket Premium	S	White	57039361265120AAGX
5080 50-03.01	CarePocket Premium	M	White	57039361265120AAGX
5080 50-05.01	CarePocket Premium	L	White	57039361265120AAGX
5080 50-07.01	CarePocket Premium	XL	White	57039361265120AAGX