

EU Declaration of Conformity		Product Family: Continence	
APPROVED BY: TYTEX A/S		VALID FROM: 2026.04.21	VERSION NO.: 1.7

EU Declaration of Conformity

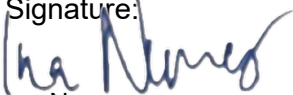
Manufacturers Name:	TYTEX A/S
Manufacturers Address:	MARSVEJ 6, 7430 IKAST, DENMARK
SRN:	DK-MF-000003620
Product Family:	Continence
Intended purpose:	Device to be worn as part of a two-piece reusable or disposable absorbent incontinence solution. For fixation of i.e. a bandage or a pad, worn as normal underwear pants.
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: <u>Class I:</u> 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

Tytex A/S
Marsvej 6,
7430 Ikast,
Denmark
www.tytex.com
+45 9660 4200

DK-Ikast 2026.04.21



MAKING HEALTHCARE MORE HUMAN

Tytex A/S
Marsvej 6
DK-7430 Ikast

Tel. +45 9660 4200

Info@tytex.dk

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Attachment to declaration of conformity Continence

Device number	Device name	Size	Color	Basic UDI-DI
Incontinence pants				
0016 59-05.01	Economy	L	White	57039361105110BAD2
0016 60-01.01	Economy	S	White	57039361105110BAD2
0016 60-03.01	Economy	M	White	57039361105110BAD2
0016 60-05.01	Economy	L	White	57039361105110BAD2
0016 60-07.01	Economy	XL	White	57039361105110BAD2
0016 60-09.01	Economy	2XL	White	57039361105110BAD2
0016 60-11.01	Economy	3XL	White	57039361105110BAD2
0016 60-13.01	Economy	4XL	White	57039361105110BAD2
0016 61-01.01	Soft Pant	S	White	57039361105110BAD2
0016 61-03.01	Soft Pant	M	White	57039361105110BAD2
0016 61-05.01	Soft Pant	L	White	57039361105110BAD2
0016 61-07.01	Soft Pant	XL	White	57039361105110BAD2
0704 50-01.01	Classic	S	White	57039361105110BAD2
0704 50-03.01	Classic	M	White	57039361105110BAD2
0704 50-05.01	Classic	L	White	57039361105110BAD2
0704 50-07.01	Classic	XL	White	57039361105110BAD2
0705 50-01.01	Allround	S	White	57039361105110BAD2
0705 50-03.01	Allround	M	White	57039361105110BAD2
0705 50-05.01	Allround	L	White	57039361105110BAD2
0705 50-07.01	Allround	XL	White	57039361105110BAD2
0708 50-03.01	Light	M	White	57039361105110BAD2
0708 50-05.01	Light	L	White	57039361105110BAD2
0708 50-07.01	Light	XL	White	57039361105110BAD2
0708 50-09.01	Light	2XL	White	57039361105110BAD2
0708 52-01.01	Light	S	White	57039361105110BAD2
0708 52-03.01	Light	M	White	57039361105110BAD2
0708 52-05.01	Light	L	White	57039361105110BAD2
0708 52-07.01	Light	XL	White	57039361105110BAD2
0708 52-09.01	Light	2XL	White	57039361105110BAD2
0708 52-11.01	Light	3XL	White	57039361105110BAD2
0710 50-01.01	Soft Pant	S	White	57039361105110BAD2
0710 50-03.01	Soft Pant	M	White	57039361105110BAD2
0710 50-05.01	Soft Pant	L	White	57039361105110BAD2
0710 50-07.01	Soft Pant	XL	White	57039361105110BAD2
0711 50-01.01	Panty	S	White	57039361105110AACX
0711 50-03.01	Panty	M	White	57039361105110AACX
0711 50-05.01	Panty	L	White	57039361105110AACX
0711 50-07.01	Panty	XL	White	57039361105110AACX
0711 50-09.01	Panty	2XL	White	57039361105110AACX
0711 50-11.01	Panty	3XL	White	57039361105110AACX
0711 54-09.01	Panty	2XL	White	57039361105110AACX
3022 53-01.01	Care Short	S	White	57039361105110AACX
3022 53-03.01	Care Short	M	White	57039361105110AACX
3022 53-05.01	Care Short	L	White	57039361105110AACX
3022 53-07.01	Care Short	XL	White	57039361105110AACX

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Device number	Device name	Size	Color	Basic UDI-DI
3234 51-01.01	Pretty Soft	S	White	57039361105110BAD2
3234 51-03.01	Pretty Soft	M	White	57039361105110BAD2
3234 51-05.01	Pretty Soft	L	White	57039361105110BAD2
3234 51-07.01	Pretty Soft	XL	White	57039361105110BAD2
3234 51-09.01	Pretty Soft	2XL	White	57039361105110BAD2
3234 51-11.01	Pretty Soft	3XL	White	57039361105110BAD2
3234 51-13.01	Pretty Soft	4XL	White	57039361105110BAD2
3234 51-15.01	Pretty Soft	5XL	White	57039361105110BAD2
3236 51-00.01	Comfort Fit	XS	White	57039361105110BAD2
3236 51-01.01	Comfort Fit	S	White	57039361105110BAD2
3236 51-03.01	Comfort Fit	M	White	57039361105110BAD2
3236 51-05.01	Comfort Fit	L	White	57039361105110BAD2
3236 51-07.01	Comfort Fit	XL	White	57039361105110BAD2
3236 51-09.01	Comfort Fit	2XL	White	57039361105110BAD2
3236 51-11.01	Comfort Fit	3XL	White	57039361105110BAD2
3246 50-01.01	Soft Support	S	White	57039361105110BAD2
3246 50-03.01	Soft Support	M	White	57039361105110BAD2
3246 50-05.01	Soft Support	L	White	57039361105110BAD2
3246 50-07.01	Soft Support	XL	White	57039361105110BAD2
3246 50-09.01	Soft Support	2XL	White	57039361105110BAD2
3246 50-11.01	Soft Support	3XL	White	57039361105110BAD2
3541 52-01.01	Incofit Panty	S	White	57039361105110CAD5
3541 52-03.01	Incofit Panty	M	White	57039361105110CAD5
3541 52-05.01	Incofit Panty	L	White	57039361105110CAD5
3541 52-07.01	Incofit Panty	XL	White	57039361105110CAD5
3541 52-09.01	Incofit Panty	2XL	White	57039361105110CAD5
3541 52-11.01	Incofit Panty	3XL	White	57039361105110CAD5
3577 54-01.01	Premium Support	S	Black	57039361105110BAD2
3577 54-03.01	Premium Support	M	Black	57039361105110BAD2
3577 54-05.01	Premium Support	L	Black	57039361105110BAD2
3577 54-07.01	Premium Support	XL	Black	57039361105110BAD2
3577 54-09.01	Premium Support	2XL	Black	57039361105110BAD2
3701 50-01.01	New Comfort Fit	S	White	57039361105110BAD2
3701 50-03.01	New Comfort Fit	M	White	57039361105110BAD2
3701 50-05.01	New Comfort Fit	L	White	57039361105110BAD2
3701 50-07.01	New Comfort Fit	XL	White	57039361105110BAD2
3701 50-09.01	New Comfort Fit	2XL	White	57039361105110BAD2
3721 50-01.01	Smart&Soft Slip	S	White	57039361105110AACX
3721 50-03.01	Smart&Soft Slip	M	White	57039361105110AACX
3721 50-05.01	Smart&Soft Slip	L	White	57039361105110AACX
3721 50-07.01	Smart&Soft Slip	XL	White	57039361105110AACX
3721 50-09.01	Smart&Soft Slip	2XL	White	57039361105110AACX
3721 50-11.01	Smart&Soft Slip	3XL	White	57039361105110AACX
3760 50-07.01	Economic Seamless Brief	XL	White	57039361105110AACX
3760 50-09.01	Economic Seamless Brief	2XL	White	57039361105110AACX
3760 50-11.01	Economic Seamless Brief	3XL	White	57039361105110AACX
3760 50-13.01	Economic Seamless Brief	4XL	White	57039361105110AACX
6001 50-01.01	Super Light	S	White	57039361105110BAD2
6001 50-03.01	Super Light	M	White	57039361105110BAD2
6001 50-05.01	Super Light	L	White	57039361105110BAD2
6001 50-07.01	Super Light	XL	White	57039361105110BAD2



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6001 50-09.01	Super Light	2XL	White	57039361105110BAD2
6014 51-01.01	New Convenience	S	White	57039361105110BAD2
6014 51-03.01	New Convenience	M	White	57039361105110BAD2
6014 51-05.01	New Convenience	L	White	57039361105110BAD2
6014 51-07.01	New Convenience	XL	White	57039361105110BAD2
6014 51-09.01	New Convenience	2XL	White	57039361105110BAD2
6052 50-00.01	New Premium	XS	White	57039361105110BAD2
6052 50-01.01	New Premium	S	White	57039361105110BAD2
6052 50-03.01	New Premium	M	White	57039361105110BAD2
6052 50-05.01	New Premium	L	White	57039361105110BAD2
6052 50-07.01	New Premium	XL	White	57039361105110BAD2
6052 50-09.01	New Premium	2XL	White	57039361105110BAD2
6052 50-11.01	New Premium	3XL	White	57039361105110BAD2
6056 50-00.01	New Standard	XS	White	57039361105110BAD2
6056 50-01.01	New Standard	S	White	57039361105110BAD2
6056 50-03.01	New Standard	M	White	57039361105110BAD2
6056 50-05.01	New Standard	L	White	57039361105110BAD2
6056 50-07.01	New Standard	XL	White	57039361105110BAD2
6056 50-09.01	New Standard	2XL	White	57039361105110BAD2
7012 50-01.01	Panty Basic	S	White	57039361105110AACX
7012 50-03.01	Panty Basic	M	White	57039361105110AACX
7012 50-05.01	Panty Basic	L	White	57039361105110AACX
7012 50-07.01	Panty Basic	XL	White	57039361105110AACX
7012 50-09.01	Panty Basic	2XL	White	57039361105110AACX
7012 50-11.01	Panty Basic	3XL	White	57039361105110AACX