


Declaration of Conformity	This document is the property of Tytex. The contents must not be disclosed to third parties without the expressed written consent from Tytex. Infringements in the above will result in prosecution.	
Product: Incontinence Pants	TGR 4.2.1.1 Appendix M	
APPROVED BY TYTEX 	VALID FROM 9. October 2018	VER. NO 1,7

DECLARATION OF CONFORMITY

According to regulations of Council Directive 93/42/EEC for medical devices, Tytex A/S hereby declares to fulfil the requirements as set out in Annex VII Technical Documentation, the essential requirements in Annex I of the above mentioned directive as well as amended regulations of Council Directive 2007/47/EC Annex II.

Incontinence pants 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.

Product name	Product No.	Size
▪ Economy	0016	S, M, L, XL, 2XL, 3XL, 4XL
▪ Soft Pant	0016	S, M, L, XL
▪ Classic	0704	S, M, L, XL
▪ Allround	0705	S, M, L, XL
▪ Light	0708	S, M, L, XL, 2XL, 3XL
▪ Soft Pant	0710	S, M, L, XL
▪ Panty	0711	S, M, L, XL, 2XL, 3XL
▪ Careshort	3022	XS, S, M, L, XL
▪ Carefit	3061	S, M, L, XL
▪ Pretty Soft	3234	S, M, L, XL, 2XL, 3XL
▪ Comfort Fit	3236	XS, S, M, L, XL, 2XL, 3XL
▪ Soft Support	3246	S, M, L, XL, 2XL, 3XL
▪ Incofit Panty	3441	S, M, L, XL, 2XL
▪ Ultra Support	3491	S, M, L, XL, 2XL
▪ Super Light	6001	S, M, L, XL
▪ New Convenience	6014	XS, S, M, L, XL, 2XL
▪ New Premium	6052	XS, S, M, L, XL, 2XL, 3XL
▪ New Standard	6056	XS, S, M, L, XL, 2XL
▪ FemFix	6079	L, XL, 2XL
▪ Panty Basic	7012	S, M, L, XL, 2XL, 3XL
▪ Panty Polyester	7021	M, L, XL
▪ Panty Polyester	7023	S, M, L, XL, 2XL, 3XL



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