


DECLARATION OF CONFORMITY

Product Name: New Standard		Product no.: 6056	
APPROVED BY TYTEX		APPROVED BY CUSTOMER	VALID FROM 30. April 2021
			VERSION NO. 1.1

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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.

Contenance pants New Standard 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.

Brand	Product name	Product No.	Size
-	New Standard	6056	S – 2XL


SRN: DK-MF-000003620

Tytex have accepted that customer Igefa Group may label the Tytex Contenance pants New Standard with own brand and name

Basic UDI-DI: 57039361105110BAD2

Tytex				Igefa Group	
Product number	Product name	Size	Colour	Product number	Product name
6056 50-03.01.V89	New Standard	M	White	2133640	Kolibri Comfix Extra
6056 50-05.01.V89	New Standard	L	White	2133642	Kolibri Comfix Extra
6056 50-07.01.V89	New Standard	XL	White	2133644	Kolibri Comfix Extra
6056 50-09.01.V89	New Standard	2XL	White	2133646	Kolibri Comfix Extra
6056 50-03.01.V90	New Standard	M	White	2133641	Kolibri Comfix Extra
6056 50-05.01.V90	New Standard	L	White	2133643	Kolibri Comfix Extra
6056 50-07.01.V90	New Standard	XL	White	2133645	Kolibri Comfix Extra
6056 50-09.01.V90	New Standard	2XL	White	2133647	Kolibri Comfix Extra

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



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