


## DECLARATION OF CONFORMITY

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

## 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.

Continence 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.


<b>Brand</b>	<b>Product name</b>	<b>Product No.</b>	<b>Size</b>
-	New Standard	6056	S – 2XL

SRN: DK-MF-000003620

Tytex have accepted that customer Igefa Group may label the Tytex Continence 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



Kim Remin Ankjaer  
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 Legal Representative

**TYTEX**  
MAKING HEALTHCARE MORE HUMAN

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