


**DECLARATION OF CONFORMITY**

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

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.

<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 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

**DECLARATION OF CONFORMITY**

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

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



Kim Remin Ankjaer  
VP of Quality & Environment  
Legal Representative

**TYTEX**  
MAKING HEALTHCARE MORE HUMAN  
Tytex A/S  
Industrivej 21  
DK-7430 Ikast

Tel. +45 9660 4200  
Fax +45 9660 4201  
info@tytex.dk

Tytex A/S  
Industrivej 21  
7430 Ikast, Denmark  
[www.tytex.com](http://www.tytex.com)  
+45 9660 4200