


<b>EU Declaration of Conformity</b>		<b>Product Family: SafeHip</b>
APPROVED BY: TYTEX A/S		VALID FROM: 2022-08-29
		VERSION NO.: 1.2

## EU Declaration of Conformity

<b>Manufacturers Name:</b>	TYTEX A/S
<b>Manufacturers Address:</b>	MARSVEJ 6, 7430 IKAST, DENMARK
<b>SRN:</b>	DK-MF-000003620
<b>Product Family:</b>	SafeHip
<b>Intended purpose:</b>	Device to be worn by elderly people as part of a preventive garment for hip protection.
<b>Classification:</b>	Class I, rule I, non-sterile
<b>Conformity assessment route:</b>	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:

DK-Ikast 2022-08-29:



Bjarke Laust  
Haagensen  
Compliance  
Manager (PRRC)


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**Attachment to declaration of conformity SAFEHIP**

Device number	Device name	Size	Color	Basic UDI-DI
<b>Hip protection</b>				
3612 50-01	SAFEHIP AirX Discreet, Male	S	White	57039361285150AAJN
3612 50-03	SAFEHIP AirX Discreet, Male	M	White	57039361285150AAJN
3612 50-05	SAFEHIP AirX Discreet, Male	L	White	57039361285150AAJN
3612 50-07	SAFEHIP AirX Discreet, Male	XL	White	57039361285150AAJN
3612 50-09	SAFEHIP AirX Discreet, Male	2XL	White	57039361285150AAJN
3612 51-01	SAFEHIP AirX Discreet, Male	S	Black	57039361285150AAJN
3612 51-03	SAFEHIP AirX Discreet, Male	M	Black	57039361285150AAJN
3612 51-05	SAFEHIP AirX Discreet, Male	L	Black	57039361285150AAJN
3612 51-07	SAFEHIP AirX Discreet, Male	XL	Black	57039361285150AAJN
3612 51-09	SAFEHIP AirX Discreet, Male	2XL	Black	57039361285150AAJN
3604 50-01	SAFEHIP AirX Discreet, Female	S	White	57039361285150AAJN
3604 50-03	SAFEHIP AirX Discreet, Female	M	White	57039361285150AAJN
3604 50-05	SAFEHIP AirX Discreet, Female	L	White	57039361285150AAJN
3604 50-07	SAFEHIP AirX Discreet, Female	XL	White	57039361285150AAJN
3604 50-09	SAFEHIP AirX Discreet, Female	2XL	White	57039361285150AAJN
3604 51-01	SAFEHIP AirX Discreet, Female	S	Black	57039361285150AAJN
3604 51-03	SAFEHIP AirX Discreet, Female	M	Black	57039361285150AAJN
3604 51-05	SAFEHIP AirX Discreet, Female	L	Black	57039361285150AAJN
3604 51-07	SAFEHIP AirX Discreet, Female	XL	Black	57039361285150AAJN
3604 51-09	SAFEHIP AirX Discreet, Female	2XL	Black	57039361285150AAJN
3365 59-00	SAFEHIP AirX, Unisex	XS	White	57039361285150AAJN
3365 59-01	SAFEHIP AirX, Unisex	S	White	57039361285150AAJN
3365 59-03	SAFEHIP AirX, Unisex	M	White	57039361285150AAJN
3365 59-05	SAFEHIP AirX, Unisex	L	White	57039361285150AAJN
3365 59-07	SAFEHIP AirX, Unisex	XL	White	57039361285150AAJN
3365 59-09	SAFEHIP AirX, Unisex	2XL	White	57039361285150AAJN
3366 50-00	SAFEHIP AirX, Female	XS	White	57039361285150AAJN
3366 50-01	SAFEHIP AirX, Female	S	White	57039361285150AAJN
3366 50-03	SAFEHIP AirX, Female	M	White	57039361285150AAJN
3366 50-05	SAFEHIP AirX, Female	L	White	57039361285150AAJN
3366 50-07	SAFEHIP AirX, Female	XL	White	57039361285150AAJN
3366 50-09	SAFEHIP AirX, Female	2XL	White	57039361285150AAJN
3367 50-00	SAFEHIP AirX, Male	XS	White	57039361285150AAJN
3367 50-01	SAFEHIP AirX, Male	S	White	57039361285150AAJN
3367 50-03	SAFEHIP AirX, Male	M	White	57039361285150AAJN
3367 50-05	SAFEHIP AirX, Male	L	White	57039361285150AAJN
3367 50-07	SAFEHIP AirX, Male	XL	White	57039361285150AAJN
3367 50-09	SAFEHIP AirX, Male	2XL	White	57039361285150AAJN
3368 50-00	SAFEHIP AirX, Open	XS	White	57039361285150AAJN
3368 50-01	SAFEHIP AirX, Open	S	White	57039361285150AAJN
3368 50-03	SAFEHIP AirX, Open	M	White	57039361285150AAJN
3368 50-05	SAFEHIP AirX, Open	L	White	57039361285150AAJN
3368 50-07	SAFEHIP AirX, Open	XL	White	57039361285150AAJN
3368 50-09	SAFEHIP AirX, Open	2XL	White	57039361285150AAJN
3265 50-00	SAFEHIP Classic, Unisex	XS	White	57039361285150AAJN
3265 50-01	SAFEHIP Classic, Unisex	S	White	57039361285150AAJN
3265 50-03	SAFEHIP Classic, Unisex	M	White	57039361285150AAJN
3265 50-05	SAFEHIP Classic, Unisex	L	White	57039361285150AAJN



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3265 50-07	SAFEHIP Classic, Unisex	XL	White	57039361285150AAJN
3265 50-09	SAFEHIP Classic, Unisex	2XL	White	57039361285150AAJN
3265 51-00	SAFEHIP Classic, Unisex	XS	White	57039361285150AAJN
3265 51-01	SAFEHIP Classic, Unisex	S	White	57039361285150AAJN
3265 51-03	SAFEHIP Classic, Unisex	M	White	57039361285150AAJN
3265 51-05	SAFEHIP Classic, Unisex	L	White	57039361285150AAJN
3265 51-07	SAFEHIP Classic, Unisex	XL	White	57039361285150AAJN
3265 51-09	SAFEHIP Classic, Unisex	2XL	White	57039361285150AAJN
8190 50-01	SAFEHIP Active Soft	S	White	57039361285150AAJN
8190 50-03	SAFEHIP Active Soft	M	White	57039361285150AAJN
8190 50-05	SAFEHIP Active Soft	L	White	57039361285150AAJN
8190 50-07	SAFEHIP Active Soft	XL	White	57039361285150AAJN
8190 50-09	SAFEHIP Active Soft	2XL	White	57039361285150AAJN
0761 50-99	Classic Sheild	One Size	N/A	57039361285155AAKF
8110 50-99	AirX Sheild	One Size	N/A	57039361285155AAKF
8130 50-99	AirX Discreet Sheild	One Size	N/A	57039361285155AAKF