


DECLARATION OF CONFORMITY

Product Name: Post-Op Bra, Alice		Product no.: 3291	
APPROVED BY TYTEX		APPROVED BY CUSTOMER	VALID FROM 01. November 2020
		VERSION NO. 1.0	

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.

The Post-Op Bra, Alice are class I, rule I, non-sterile CE marked products intended for fixation of a bandage or another medical device for post-surgical use and for comfortable wear for a maximum of wound and scar protection.

Product number	Product name	Size	Colour	Basic UDI-DI
3291 60-01	Post-Op Bra, Alice	S	White	57039361265170AAJ2
3291 60-03	Post-Op Bra, Alice	M	White	57039361265170AAJ2
3291 60-05	Post-Op Bra, Alice	L	White	57039361265170AAJ2
3291 60-07	Post-Op Bra, Alice	XL	White	57039361265170AAJ2
3291 60-09	Post-Op Bra, Alice	2XL	White	57039361265170AAJ2
3291 61-01	Post-Op Bra, Alice	S	Black	57039361265170AAJ2
3291 61-03	Post-Op Bra, Alice	M	Black	57039361265170AAJ2
3291 61-05	Post-Op Bra, Alice	L	Black	57039361265170AAJ2
3291 61-07	Post-Op Bra, Alice	XL	Black	57039361265170AAJ2
3291 61-09	Post-Op Bra, Alice	2XL	Black	57039361265170AAJ2
3291 62-01	Post-Op Bra, Alice	S	Tan	57039361265170AAJ2
3291 62-03	Post-Op Bra, Alice	M	Tan	57039361265170AAJ2
3291 62-05	Post-Op Bra, Alice	L	Tan	57039361265170AAJ2
3291 62-07	Post-Op Bra, Alice	XL	Tan	57039361265170AAJ2
3291 62-09	Post-Op Bra, Alice	2XL	Tan	57039361265170AAJ2

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




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DECLARATION OF CONFORMITY

Product Name: Post-Op Bra, Sophia		Product no.: 3342	
APPROVED BY TYTEX		APPROVED BY CUSTOMER	VALID FROM 01. November 2020
		VERSION NO. 1.0	

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.

The Post-Op Bra, Sophia are class I, rule I, non-sterile CE marked products intended for fixation of a bandage or another medical device for post-surgical use and for comfortable wear for a maximum of wound and scar protection.

Product number	Product name	Size	Colour	Basic UDI-DI
3342 60-01	Post-Op Bra, Sophia	S	White	57039361265170ACJ6
3342 60-03	Post-Op Bra, Sophia	M	White	57039361265170ACJ6
3342 60-05	Post-Op Bra, Sophia	L	White	57039361265170ACJ6
3342 60-07	Post-Op Bra, Sophia	XL	White	57039361265170ACJ6
3342 60-09	Post-Op Bra, Sophia	2XL	White	57039361265170ACJ6
3342 60-11	Post-Op Bra, Sophia	3XL	White	57039361265170ACJ6
3342 61-01	Post-Op Bra, Sophia	S	Black	57039361265170ACJ6
3342 61-03	Post-Op Bra, Sophia	M	Black	57039361265170ACJ6
3342 61-05	Post-Op Bra, Sophia	L	Black	57039361265170ACJ6
3342 61-07	Post-Op Bra, Sophia	XL	Black	57039361265170ACJ6
3342 61-09	Post-Op Bra, Sophia	2XL	Black	57039361265170ACJ6
3342 61-11	Post-Op Bra, Sophia	3XL	Black	57039361265170ACJ6

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DECLARATION OF CONFORMITY			
Product Name: Post-Op Bra, Mary		Product no.: 3343	
APPROVED BY TYTEX		APPROVED BY CUSTOMER	VALID FROM 01. November 2020
		VERSION NO. 1.0	


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.

The Post-Op Bra, Mary are class I, rule I, non-sterile CE marked products intended for fixation of a bandage or another medical device for post-surgical use and for comfortable wear for a maximum of wound and scar protection.

Product number	Product name	Size	Colour	Basic UDI-DI
3343 60-01	Post-Op Bra, Mary	S	White	57039361265170AAJ2
3343 60-03	Post-Op Bra, Mary	M	White	57039361265170AAJ2
3343 60-05	Post-Op Bra, Mary	L	White	57039361265170AAJ2
3343 60-07	Post-Op Bra, Mary	XL	White	57039361265170AAJ2
3343 60-09	Post-Op Bra, Mary	2XL	White	57039361265170AAJ2
3343 60-11	Post-Op Bra, Mary	3XL	White	57039361265170AAJ2
3343 60-13	Post-Op Bra, Mary	4XL	White	57039361265170AAJ2
3343 61-01	Post-Op Bra, Mary	S	Black	57039361265170AAJ2
3343 61-03	Post-Op Bra, Mary	M	Black	57039361265170AAJ2
3343 61-05	Post-Op Bra, Mary	L	Black	57039361265170AAJ2
3343 61-07	Post-Op Bra, Mary	XL	Black	57039361265170AAJ2
3343 61-09	Post-Op Bra, Mary	2XL	Black	57039361265170AAJ2
3343 61-11	Post-Op Bra, Mary	3XL	Black	57039361265170AAJ2
3343 61-13	Post-Op Bra, Mary	4XL	Black	57039361265170AAJ2
3343 62-01	Post-Op Bra, Mary	S	Tan	57039361265170AAJ2
3343 62-03	Post-Op Bra, Mary	M	Tan	57039361265170AAJ2
3343 62-05	Post-Op Bra, Mary	L	Tan	57039361265170AAJ2
3343 62-07	Post-Op Bra, Mary	XL	Tan	57039361265170AAJ2
3343 62-09	Post-Op Bra, Mary	2XL	Tan	57039361265170AAJ2
3343 62-11	Post-Op Bra, Mary	3XL	Tan	57039361265170AAJ2
3343 62-13	Post-Op Bra, Mary	4XL	Tan	57039361265170AAJ2

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DECLARATION OF CONFORMITY			
Product Name: Post-Op Bra, Mary		Product no.: 3343	
APPROVED BY TYTEX		APPROVED BY CUSTOMER	VALID FROM 01. November 2020
		VERSION NO. 1.0	



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DECLARATION OF CONFORMITY			
Product Name: Post-Op Bra, Marianne		Product no.: 3373	
APPROVED BY TYTEX		APPROVED BY CUSTOMER	VALID FROM 11. February 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.

The Post-Op Bra, Marianne are class I, rule I, non-sterile CE marked products intended for fixation of a bandage or another medical device for post-surgical use and for comfortable wear for a maximum of wound and scar protection.

Product number	Product name	Size	Colour	Basic UDI-DI
3373 60-01	Post-Op Bra, Marianne	S	White	57039361265170AAJ2
3373 60-03	Post-Op Bra, Marianne	M	White	57039361265170AAJ2
3373 60-05	Post-Op Bra, Marianne	L	White	57039361265170AAJ2
3373 60-07	Post-Op Bra, Marianne	XL	White	57039361265170AAJ2
3373 60-09	Post-Op Bra, Marianne	2XL	White	57039361265170AAJ2

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DECLARATION OF CONFORMITY

Product Name: Post-Op Bra, Ava		Product no.: 3444	
APPROVED BY TYTEX	<i>Jak</i>	APPROVED BY CUSTOMER	VALID FROM 01. November 2020
		VERSION NO. 1.0	


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.

The Post-Op Bra, Ava are class I, rule I, non-sterile CE marked products intended for fixation of a bandage or another medical device for post-surgical use and for comfortable wear for a maximum of wound and scar protection.

Product number	Product name	Size	Cup size	Colour	Basic UDI-DI
3444 60-01	Post-Op Bra, Ava	S	A-C	White	57039361265170ACJ6
3444 60-03	Post-Op Bra, Ava	M	A-C	White	57039361265170ACJ6
3444 60-05	Post-Op Bra, Ava	L	A-C	White	57039361265170ACJ6
3444 60-07	Post-Op Bra, Ava	XL	A-C	White	57039361265170ACJ6
3444 60-09	Post-Op Bra, Ava	2XL	A-C	White	57039361265170ACJ6
3444 61-01	Post-Op Bra, Ava	S	A-C	Black	57039361265170ACJ6
3444 61-03	Post-Op Bra, Ava	M	A-C	Black	57039361265170ACJ6
3444 61-05	Post-Op Bra, Ava	L	A-C	Black	57039361265170ACJ6
3444 61-07	Post-Op Bra, Ava	XL	A-C	Black	57039361265170ACJ6
3444 61-09	Post-Op Bra, Ava	2XL	A-C	Black	57039361265170ACJ6
3444 62-01	Post-Op Bra, Ava	S	A-C	Tan	57039361265170ACJ6
3444 62-03	Post-Op Bra, Ava	M	A-C	Tan	57039361265170ACJ6
3444 62-05	Post-Op Bra, Ava	L	A-C	Tan	57039361265170ACJ6
3444 62-07	Post-Op Bra, Ava	XL	A-C	Tan	57039361265170ACJ6
3444 62-09	Post-Op Bra, Ava	2XL	A-C	Tan	57039361265170ACJ6

DECLARATION OF CONFORMITY

Product Name: Post-Op Bra, Ava		Product no.: 3444	
APPROVED BY TYTEX		APPROVED BY CUSTOMER	VALID FROM 01. November 2020
			VERSION NO. 1.0

Product number	Product name	Size	Cup size	Colour	Basic UDI-DI
3444 63-01	Post-Op Bra, Ava	S	D-F	White	57039361265170ACJ6
3444 63-03	Post-Op Bra, Ava	M	D-F	White	57039361265170ACJ6
3444 63-05	Post-Op Bra, Ava	L	D-F	White	57039361265170ACJ6
3444 63-07	Post-Op Bra, Ava	XL	D-F	White	57039361265170ACJ6
3444 63-09	Post-Op Bra, Ava	2XL	D-F	White	57039361265170ACJ6
3444 64-01	Post-Op Bra, Ava	S	D-F	Black	57039361265170ACJ6
3444 64-03	Post-Op Bra, Ava	M	D-F	Black	57039361265170ACJ6
3444 64-05	Post-Op Bra, Ava	L	D-F	Black	57039361265170ACJ6
3444 64-07	Post-Op Bra, Ava	XL	D-F	Black	57039361265170ACJ6
3444 64-09	Post-Op Bra, Ava	2XL	D-F	Black	57039361265170ACJ6
3444 65-01	Post-Op Bra, Ava	S	D-F	Tan	57039361265170ACJ6
3444 65-03	Post-Op Bra, Ava	M	D-F	Tan	57039361265170ACJ6
3444 65-05	Post-Op Bra, Ava	L	D-F	Tan	57039361265170ACJ6
3444 65-07	Post-Op Bra, Ava	XL	D-F	Tan	57039361265170ACJ6
3444 65-09	Post-Op Bra, Ava	2XL	D-F	Tan	57039361265170ACJ6

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DECLARATION OF CONFORMITY

Product Name: Post-Op Bra, Lisa		Product no.: 3471	
APPROVED BY TYTEX		APPROVED BY CUSTOMER	VALID FROM 01. November 2020
			VERSION NO. 1.0


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.

The Post-Op Bra, Lisa are class I, rule I, non-sterile CE marked products intended for fixation of a bandage or another medical device for post-surgical use and for comfortable wear for a maximum of wound and scar protection.

Product number	Product name	Size	Cup size	Colour	Basic UDI-DI
3471 54-01	Post-Op Bra, Lisa	S	AA-B	White	57039361265170ACJ6
3471 54-03	Post-Op Bra, Lisa	M	AA-B	White	57039361265170ACJ6
3471 54-05	Post-Op Bra, Lisa	L	AA-B	White	57039361265170ACJ6
3471 54-07	Post-Op Bra, Lisa	XL	AA-B	White	57039361265170ACJ6
3471 54-09	Post-Op Bra, Lisa	2XL	AA-B	White	57039361265170ACJ6
3471 54-11	Post-Op Bra, Lisa	3XL	AA-B	White	57039361265170ACJ6
3471 55-01	Post-Op Bra, Lisa	S	AA-B	Black	57039361265170ACJ6
3471 55-03	Post-Op Bra, Lisa	M	AA-B	Black	57039361265170ACJ6
3471 55-05	Post-Op Bra, Lisa	L	AA-B	Black	57039361265170ACJ6
3471 55-07	Post-Op Bra, Lisa	XL	AA-B	Black	57039361265170ACJ6
3471 55-09	Post-Op Bra, Lisa	2XL	AA-B	Black	57039361265170ACJ6
3471 55-11	Post-Op Bra, Lisa	3XL	AA-B	Black	57039361265170ACJ6
3471 58-01	Post-Op Bra, Lisa	S	AA-B	White	57039361265170ACJ6
3471 58-03	Post-Op Bra, Lisa	M	AA-B	White	57039361265170ACJ6
3471 58-05	Post-Op Bra, Lisa	L	AA-B	White	57039361265170ACJ6
3471 58-07	Post-Op Bra, Lisa	XL	AA-B	White	57039361265170ACJ6
3471 58-09	Post-Op Bra, Lisa	2XL	AA-B	White	57039361265170ACJ6
3471 58-11	Post-Op Bra, Lisa	3XL	AA-B	White	57039361265170ACJ6

DECLARATION OF CONFORMITY

Product Name: Post-Op Bra, Lisa		Product no.: 3471	
APPROVED BY TYTEX		APPROVED BY CUSTOMER	VALID FROM 01. November 2020
		VERSION NO. 1.0	

Product number	Product name	Size	Cup size	Colour	Basic UDI-DI
3471 56-01	Post-Op Bra, Lisa	S	C-E	White	57039361265170ACJ6
3471 56-03	Post-Op Bra, Lisa	M	C-E	White	57039361265170ACJ6
3471 56-05	Post-Op Bra, Lisa	L	C-E	White	57039361265170ACJ6
3471 56-07	Post-Op Bra, Lisa	XL	C-E	White	57039361265170ACJ6
3471 56-09	Post-Op Bra, Lisa	2XL	C-E	White	57039361265170ACJ6
3471 56-11	Post-Op Bra, Lisa	3XL	C-E	White	57039361265170ACJ6
3471 57-01	Post-Op Bra, Lisa	S	C-E	Black	57039361265170ACJ6
3471 57-03	Post-Op Bra, Lisa	M	C-E	Black	57039361265170ACJ6
3471 57-05	Post-Op Bra, Lisa	L	C-E	Black	57039361265170ACJ6
3471 57-07	Post-Op Bra, Lisa	XL	C-E	Black	57039361265170ACJ6
3471 57-09	Post-Op Bra, Lisa	2XL	C-E	Black	57039361265170ACJ6
3471 57-11	Post-Op Bra, Lisa	3XL	C-E	Black	57039361265170ACJ6

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DECLARATION OF CONFORMITY			
Product Name: Breast Puffs		Product no.: 8108	
APPROVED BY TYTEX		APPROVED BY CUSTOMER	VALID FROM 01. October 2020
		VERSION NO. 1.0	

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.

The Breast Puffs are class 1, rule 1; non-sterile CE marked products with intended use as textile device used to replace the female breast typically after a mastectomy.

Product number	Product name	Size	Colour	Basic UDI-DI
8108 50-99	Breast Puffs	One Size	White	57039361265170ADJ8

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DECLARATION OF CONFORMITY

Product Name: Implant Stabilizer Band		Product no.: 8113	
APPROVED BY TYTEX		APPROVED BY CUSTOMER	VALID FROM 01. October 2020
		VERSION NO. 1.0	

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.

The Implant Stabilizer band are class 1, rule 1; non-sterile CE marked products with intended use as a compression band to stabilize and keep breast implants in place after surgery.


Product number	Product name	Size	Colour	Basic UDI-DI
8113 50-99	Implant Stabilizer Band	One Size	White	57039361265170BAJ5
8113 50-99	Implant Stabilizer Band	One Size	Black	57039361265170BAJ5

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