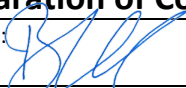




MAKING HEALTHCARE MORE HUMAN

EU Declaration of Conformity		Product Family: Wound care	
APPROVED BY: TYTEX A/S		VALID FROM: 2024-02-26	VERSION NO.: 1.4

EU Declaration of Conformity

Manufacturers Name: TYTEX A/S

Manufacturers Address: MARSVEJ 6, 7430 IKAST, DENMARK

SRN: DK-MF-000003620

Product Family: Wound Care

Brand Carefix

Intended purpose: Elastic dressing used for support and fixation of another medical device on a body part or limb of a human being.

Classification: Class I, rule I, non-sterile


Conformity assessment route: TYTEX A/S uses the following procedures for the CE-labeling of their products according the Regulation MDR 2017/745:

Class I: 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:


Bjarke Laust Haagensen
Compliance Manager
(PRRC)

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DK-Ikast 2024.02.26:



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Attachment to declaration of conformity Wound care

Device number	Device name	Size	Color	Basic UDI-DI
Wound fixation				
0151 51-00	Tube	XS	White	57039361265200AAGU
0151 51-01	Tube	S	White	57039361265200AAGU
0151 51-03	Tube	M	White	57039361265200AAGU
0151 52-05	Tube	L	White	57039361265200AAGU
0151 52-07	Tube	XL	White	57039361265200AAGU
0161 50-01	Finger-Toe	S	White	57039361265200AAGU
0161 50-03	Finger-Toe	M	White	57039361265200AAGU
0161 50-05	Finger-Toe	L	White	57039361265200AAGU
0170 50-01	Head	S	White	57039361265200AAGU
0170 50-03	Head	M	White	57039361265200AAGU
0170 50-05	Head	L	White	57039361265200AAGU
0170 50-07	Head	XL	White	57039361265200AAGU
0186 50-99	Headband	One Size	White	57039361265200AAGU