DECLARATION OF CONFORMITY			
Product Name: Tube		**Product no.:** 0151	
APPROVED BY TYTEX	APPROVED BY CUSTOMER	VALID FROM 23. June 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.

Wound Care products Tube are Class I, rule I, non-Sterile elastic dressing intended for support and fixation of another medical device on a body part or limb of a human being.

Brand: Carefix

Product number	Product name	Size	Basic UDI-DI
0151 51-00	Tube	XS	57039361265200AAGU
0151 51-01	Tube	S	57039361265200AAGU
0151 51-03	Tube	M	57039361265200AAGU
0151 52-03	Tube	M	57039361265200AAGU
0151 52-05	Tube	L	57039361265200AAGU
0151 52-07	Tube	XL	57039361265200AAGU

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

TYTEX
MAKING HEALTHCARE MORE HUMAN
Tytex A/S
Industrivej 21
DK-7430 Ikast
Tel. +45 9660 4200
Fax +45 9660 4201
info@tytex.dk

Kim Remin Ankjaer
VP of Quality & Environment
Legal Representative

Tytex A/S
Industrivej 21
7430 Ikast
Denmark
www.tytex.com
+45 9660 4200