

EU DECLARATION OF CONFORMITY

MANUFACTURER: ERMED TIP MEDICAL TIC AŞ

ADDRESS: KÖSEKÖY MAH. YILMAZ SOK. NO:15/1 KARTEPE-KOCAELI, TURKEY

Tel: 0.262.2234480

Product name: GAUZE BANDAGE

Model: Is stated in the appendix.

GMDN: 15047

Purpose of use : The dressing placed on the wound is used to wrap the cloth or support the bandage.

Basic UDI-DI: 86820760EASY038R8

Class: Class I-Other (sterile and without measuring function)

Directive: 2017/745 (Medical Device Regulations)

Conformity Assessment Rule: October 2017/745 (Medical Device Regulation) annex-IV declaration of conformity (annex II & III)

Standards applied: EN ISO 13485 :2016, TS EN ISO 14971: 2013. EN 1041 / A1:] 014, TS EN ISO 15223-i: 2016, DIN EN 6011994. EN 62366-1 / AC:2016: 2018, MEDDEV 2.12.1 REV.08. MEDDEV 2.7.1 REV.04. NBOG 2010-1

WITH THIS DOCUMENT, WE DECLARE THAT THE PRODUCTS MENTIONED ABOVE COMPLY WITH THE PROVISIONS OF THE MEDICAL DEVICE REGULATION 2017/745 ON MEDICAL DEVICES. ALL SUPPORTING DOCUMENTS ARE KEPT IN THE MANUFACTURER'S BUILDINGS. WE DECLARE THAT OUR PRODUCTS DO NOT CONTAIN HUMAN BLOOD, ANIMAL SKIN, OR PRODUCTS DERIVED FROM THESE PRODUCTS.

ERMED TIP MEDİKAL TİCARET A.Ş.
Köseköy Mahallesi Yılmaz Sok. No:15/1
Kartepe / KOCAELİ Tel: 0262-223 44 80
Alemdar V.D. 3640490515
Mersis No: 0364049051500001

PLACE, DATE: Kocaeli, 02.01.2022

ERAY KARATAŞ

Company Director

APPENDIX – MODELS

PRODUCT	SIZE	REF NO
GAUZE BANDAGE	5cm x 1.5mt	EASY411078
GAUZE BANDAGE	5cm x 5mt	EASY411084
GAUZE BANDAGE	5cm x 10mt	EASY411085
GAUZE BANDAGE	7cm x 1.5mt	EASY411102
GAUZE BANDAGE	7cm x 5mt	EASY411108
GAUZE BANDAGE	7cm x 10mt	EASY411109
GAUZE BANDAGE	10cm x 1.5mt	EASY411126
GAUZE BANDAGE	10cm x 5mt	EASY411132
GAUZE BANDAGE	10cm x 10mt	EASY411135
GAUZE BANDAGE	10cm x 100mt	EASY411144
GAUZE BANDAGE	14cm x 7mt	EASY411418
GAUZE BANDAGE	15cm x 1.5mt	EASY411146
GAUZE BANDAGE	15cm x 5mt	EASY411152
GAUZE BANDAGE	15cm x 10mt	EASY411155
GAUZE BANDAGE	15cm x 100mt	EASY411164
GAUZE BANDAGE	20cm x 1.5mt	EASY411166
GAUZE BANDAGE	20cm x 5mt	EASY411172
GAUZE BANDAGE	20cm x 10mt	EASY411175
GAUZE BANDAGE	20cm x 100mt	EASY411184
GAUZE BANDAGE	90cm x 100mt	EASY411358

ERMED TIP MEDİKAL TİCARET A.Ş.
Köseköy Mahallesi Yılmaz Sok. No:15/1
Kartepe / KOCAELİ Tel: 0262 223 44 80
Akanlar V.D. 3640490515
Merkezi No: 0364049051500001