



EC



DECLARATION OF CONFORMITY

COMPANY NAME : BRBEN TEKSTİL SANAYİ VE TİCARET ANONİM ŞİRKETİ
MANUFACTURER ADDRESS : OSB Mah 83207 Nolu Cd No:2 ŞEHİTKAMİL/G.ANTEP/ TÜRKİYE
PRODUCT NAME : DISPOSABLE SURGICAL JACKET
BRAND : BRMED
SRN NO : TR-MF-000021341
MODEL : BRGLM-001
BASIC UDI : 868303626BRGLM-001C5
CLASS-REGULATION : CLASS I-MDR (2017/745-EK IV)
REFERENCES : EKOTEKS LAB.

BELGELER

ORGANIZATIONS	PRODUCT NAME	MODEL NO	COLOR	CERTIFICATE NO	DATE OF ISSUE	VALIDITY DATE
EKOTEKS	SURGICAL JACKET	BRGLM-001	BLUE	22022155	09.09.2021	09.09.2026

PRODUCT STANDARD SCOPE : The standards given below show the test content standard made for the product. The relevant document can be provided by the organization.

ISO 17025:2017	EN 13795-1:2019	EN 29073-3	ISO 14644-1
ISO 13938-1:2019	ISO 811:2018	ISO 9073-10: 2003	ATCC 9372
EN ISO 11737-1:2018	BS EN ISO 22610: 2018	ISO 22612:2005	EN 13795
ISO 13485:2016	ISO 14001:2015	ISO 9001:2015	ISO 45001:2018

THIS EU DECLARATION OF CONFORMITY IS SOLELY THE RESPONSIBILITY OF THE MANUFACTURER. I HERE BY CONFIRMS MY ACCEPTANCE OF THE COUNCIL ON MEDICAL DEVICES AND THE EUROPEAN PARLIAMENT (EU) 2017/745 DATED APRIL 2017 APPLICABLE PROVISIONS OF THE COUNCIL AND EU REGULATION. ALL SUPPORTING DOCUMENTS EVIDENT OF COMPLIANCE WITH THE ABOVE DIRECTIVE ARE PROTECTED BY "BRBEN TEKSTİL SANAYİ VE TİCARET ANONİM ŞİRKETİ". THIS STATEMENT IS APPLICABLE TO ALL DEVICES MADE AFTER THE SIGNING DATE.

HARMONIZED STANDARD : EN ISO 13485
EN ISO 13485 CERTIFICATE NO : 21.02.301-MD
EN ISO 13485 PUBLICATION DATE : 09-04-2021
EN ISO 13485 VALIDITY DATE : 08-04-2024
CERTIFICATE PERIOD : 3 YIL
ACCREDITED APPROVED ORG. : INSPECT Uluslararası Belgelendirme Ve Gözetim Hiz Tic Ltd Şti
ADDRESS : İncilıpnar Mh Ekip İş Merkezi Kat 6 No 33 ŞEHİTKAMİL
GAZİANTEP-TÜRKİYE

CHAIRMAN OF THE BOARD
ADEM ALTAN
05.10.2022

