



EC

# DECLARATION OF CONFORMITY

COMPANY NAME : BRBEN TEKSTİL SANAYİ VE TİCARET ANONİM ŞİRKETİ  
MANUFACTURER ADDRESS : OSB 2. Bölge 83207 Cd. No:2 ŞEHİTKAMİL/GAZİANTEP/TÜRKİYE  
PRODUCT NAME : DISPOSABLE SURGICAL GOWN-SMS 40GR  
BRAND : BRMED  
SRN NO : TR-MF-000021341  
MODEL : TLM-003  
BASIC UDI : 868303626TLM-003N7  
CLASS-REGULATION : CLASS I-MDR (2017/745-EK IV)  
REFERENCES : EKOTEKS LAB.

DOCUMENTS						
ORGANIZATIONS	PRODUCT NAME	MODEL NO	COLOR	REPORT NO	DATE OF ISSUE	VALIDITY DATE
EKOTEKS	BRMED DISPOSABLE SURGICAL GOWN-SMS 40GR	TLM-003	BLUE	20016274	22.05.2020	22.05.2025
			BLUE	21017969	04.06.2021	04.06.2026

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.

EN 13795-1:2019	EN ISO 15223-1:2021	BS EN 22610:2006	ISO 811:2018	ISO 14644-1
ATCC 9372	ISO 13938-1	EN 29073-3	ISO 9073-10:2003	EN ISO 11737-1:2018
ATCC 29213	EN 1041:2008+A1:2013	ISO 17025:2017	ISO 9001:2015	ISO 17025
ISO 13485	EN ISO 20417:2021	ISO 14001:2015	ISO 45001:2018	ISO 22612:2005

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 STANDARDS : 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  
ACCREDITED APPROVED ORG. : INSPECT Uluslararası Belgelendirme Ve Gözetim Hiz Tic Ltd Şti  
ADDRESS : İncilipınar Mh Ekip İş Merkezi Kat 6 No 33 ŞEHİTKAMİL  
GAZİANTEP-TÜRKİYE

CHAIRMAN OF THE BOARD  
ADEM ALTAN

15.01.2023

