



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 SCRUB SUIT  
BRAND : BRMED  
MODEL : BRSUIT-001  
SRN NO : TR-MF-000021341  
BASIC UDI : 868303626BRSUIT-001HA  
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 SCRUB SUIT	BRSUIT-001	BEYAZ	21016191	31.05.2021	31.05.2026
			MAVİ	21016190	31.05.2021	31.05.2026

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 ISO 13485	EN 13034:2005+A1:2009	EN 13938-2:2020	ATCC 9372
EN 811:2018	EN 14605:2005+A1:2009	EN 22610:2006	ISO 13485:2016
EN 13795-1:2019	EN 14126:2003+AC:2004	EN 22612:2005	ISO 14001:2015
EN 29073-3	ISO 13938-1	ISO 9073-10:2003	ISO 9001:2015
ISO 14644-1	EN ISO 11737-1:2018	ATCC 29213	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 : İncilipınar Mh Ekip İş Merkezi Kat 6 No 33 ŞEHİTKAMİL  
GAZİANTEP-TÜRKİYE

CHAIRMAN OF THE BOARD  
ADEM ALTAN

05.10.2022

