



EC

DECLARATION OF CONFORMITY

COMPANY NAME : BRBEN TEKSTİL SANAYİ VE TİCARET ANONİM ŞİRKETİ
MANUFACTURER ADDRESS : Organize Sanayi Bölgesi Mahallesi (Osb 2. Bölge)
83207 Nolu Cd. No:2 ŞEHİTKAMİL/GAZİANTEP/TÜRKİYE
PRODUCT NAME : DISPOSABLE JUMPSUIT-SMS NONWOVEN
SRN NO : TR-MF-000021341
BRAND : BRMED
MODEL : BRTLM 003
BASIC UDI : 868303626BRTLM-003K6
CLASS-REGULATION : CLASS I-MDR (2017/745-EK IV)
REFERENCES : Ekoteks : Certificate No. 21016193
PRODUCT STANDARD SCOPE :

EN 13795-1:2019	EN 29073-3	ISO 17025:2017
EN 811:2018	ISO 9073-10	ATCC 9372
EN ISO 11737-1	EN ISO 22610:2006	ISO 13938-1
ISO 13485:2016	ISO 9001:2015	ISO 14644-1
ISO 14001:2015	ISO 45001:2018	ISO 22612:2015

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

