



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 MEDICAL FACE MASK
BRAND : BRMED
SRN NO : TR-MF-000021341
BASIC UDI : 868303626BR3PLY-27CT
CLASS-REGULATION : CLASS I-MDR (2017/745-EK IV)
REFERENCES : OEKO-TEX /EKOTEST LAB.

DOCUMENTS

ORGANIZATIONS	PRODUCT NAME	MODEL NO	COLORS	CERTIFICATE NO	ISSUE DATE	VALIDITY DATE
EKOTEKS	BRMED Medical Face Mask	BR3PLY-27	WHITE	21027429	20.09.2021	20.09.2026
			NAVY BLUE	21027430-RER	20.09.2021	20.09.2026
			BURGUNDY	21033491	16.11.2021	16.11.2026
			GREY	21033493	16.11.2021	16.11.2026
			PINK	21033494	16.11.2021	16.11.2026
			BLACK	21027429	20.09.2021	20.09.2026
OEKO-TEX			ALL COLORS	2022OK0810	19.09.2022	30.04.2023

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 14683:2019+AC	EN ISO 11737-1:2018	ISO 22609:2004
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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



Client Name and address

Müşteri ismi ve adresi

BRBEN TEKSTİL SAN. VE TİC. A.Ş.

2. ORGANİZE SANAYİ BÖLGESİ 83207 NOLU CADDE NO:2/10
ŞEHİTKAMİL / GAZİANTEP

Standard
Standard

ISO 13485:2016 Quality Management Systems-Medical Devices

INSPECT assessed and approved that related firm meets the requirements of the designated standard at related scope
INSPECT ilgili kuruluşun yukarıda belirtilen standardın gerekliliklerine uygunluğunu ilgili kapsamda testler yapıp onaylamaktadır.

Scope
Kapsam

TEK KULLANIMLIK İŞ ELBİSESİ İMALATI VE SATIŞI

MANUFACTURING AND SELLING OF SINGLE USE PROTECTIVE CLOTH

EA/Category Code: A

Initial issue date: 09.Apr.2021

Issue date of this certificate: 09.Apr.2021

Validity of this certificate: 08.Apr.2022

Recertification date: 08.Apr.2024

Certificate No: 21.02.301-MD


Genel Müdür

To verify the validity of this certificate please visit: www.inspect.com.tr
Bu sertifikayı geçerliliğini kontrol etmek için lütfen www.inspect.com.tr'yi ziyaret ediniz.

The validity of this certificate is depend on the success of surveillance assessments.
Bu belgenin geçerliliği ara denetimlerin başarı ile yapılmasına bağlıdır.

