



EC

DECLARATION OF CONFORMITY

COMPANY NAME : BRBEN TEKSTİL SANAYİ VE TİCARET ANONİM ŞİRKETİ
MANUFACTURER ADDRESS : OSB 2. BÖLGE 83207 CD. NO:2 ŞEHİTKAMİL/GAZİANTEP
PRODUCT NAME : DISPOSABLE PROTECTIVE MASK-FFP2
BRAND : BRMED
SRN NO : TR-MF-000021341
MODEL : BR1MSK-001
BASIC NO : 868303626BR1MSK-001SB
CLASS-REGULATION : CLASS I-MDR (2017/745-EK IV)
REFERENCES :

| TEST REPORT NO | | | | |
|----------------|------------|------------------------------------|-------------|---|
| PRODUCT TYPES | OEKO-TEX | EUROLAB Lab. | MNA Lab. | PRS |
| FFP2 | 2022OK0810 | 2022250227 (EN 14683+AC 2019) | M-2022-0512 | 1. CL/PCLB8/1/6/2021 2. CL/PCLB8/10/2023 |
| | | 2022031520 (PFE AND EN 13274-7) | | |

PRODUCT STANDARD SCOPE :

| | | |
|---------------------|------------------|-----------------|
| EN 149:2001+A1:2009 | EN 14683+AC 2019 | EN 13274-7:2008 |
| ISO 22609 | EN ISO 11737-1 | TS ISO 811 |
| EN ISO 13965-2 | TS EN 659 -A1 | ISO 139 |
| ISO 13485:2016 | ISO 9001:2015 | GB 18401:2010 |
| ISO 14001:2015 | ISO 45001:2018 | ISO 17050-1 |

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

