

BRBEN TEKSTİL SANAYİ VE TİCARET A.Ş.

EU DECLARATION OF CONFORMITY

MANUFACTURER

BRBEN TEKSTİL SANAYİ VE TİCARET A.Ş.

2.Organize San.Bölg.Celal Doğan Bulv.no:25 Başpınar Şehitkamil Gaziantep Turkey

GMDN CODE: 35177 (SURGICAL FACE MASK, SINGLE USE)

UMDNS CODE:1229 (MASK, SURGICAL)

MODEL, IDENTIFICATION NUMBER:BR3PLY-27

PRODUCT STANDARTS: EN 14683:2019+AC 2019

UDI-DI NO: 868303626BR3PLY-27CT

PARAMETRES: 3 PLY NON-WOVEN SPUNBOND MELTBLOWN MATERIAL BLUE

, WITH ADJUSTABLE NOSE WIRES, ANTI-ALLERGIC AIR IRRIGATION, EASY BREATHABLE, ULTROSONIC STITCHING, WITHOUT FIBER GLASS AND LATEX

DEVICE CLASSIFICATION: CLASS I (NON-STERILE, NON- MEASURING AND NON-MEASURING) , RULE 1 PER ANNEX IV (EX 2017/745-ANNEX IV)

THIS EU DECLARATION OF CONFORMITY IS ISSUED ONLY UNDER THE RESPONSIBILITY OF THE MANUFACTURER. I, THE UNDERSIGNED, HEREBY DECLARE THAT THE SPECIFIED MEDICAL DEVICE(S) MEET(S) THE APPLICABLE PROVISIONS OF REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL OF 5 APRIL 2017 ON MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION THAT CONTAINS PROOF OF COMPLIANCE TO THE AFOREMENTIONED DIRECTIVE(S) IS RETAINED UNDER THE PREMISES OF "BRBEN TEKSTİL SAN VE TİC AŞ.". THIS DECLARATION APPLIES TO ALL DEVICES FROM THE SIGNATURE DATE FORWARD.

This decalration is prepared according to the test results in Ekoteks Laboratory for the; EN 14683:2019-ANNEX C-MEDICAL, Microbiology EN14683:2019+AC:2019-ANNEX B MEDICAL Microbiology ISO11737-1:2018/AMD 1:2021-MEDICAL Chemistry ISO 22609:2004 standart.

SURGICAL MASK BARCODE NUMBERS

NO	COLOUR	SINGLE MASK	THIRTY MASK	FIFTY MASKS	TEN MASKS	UDI NUMBER
1	WHITE S. MASK	8683036263865	8683036263896	8683036263414	8683036263742	868303626BR3PLY-27CT
2	NAVY BLUE S. MASK	8683036264800	8683036264848	8683036260376	8683036264756	868303626BR3PLY-27CT
3	PINK SURGICAL MASK	8683036264831	8683036264862	8683036264725	8683036264787	868303626BR3PLY-27CT
4	GREY SURGICAL MASK	8683036264817	8683036264855	8683036264701	8683036264763	868303626BR3PLY-27CT
5	BURGUNDY S. MASK	8683036264824		8683036264718	8683036264770	868303626BR3PLY-27CT
6	BLACK S. MASK			8683036263391	8683036263728	868303626BR3PLY-27CT
7	BLUE SURGICAL MASK			8683036263407	8683036263735	868303626BR3PLY-27CT

Gaziantep, 20/07/2022

This declaration under the responsibility of the Manufacturer



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