

## EU DECLARATION OF CONFORMITY

MANUFACTURER

**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:**868303626339BR3PLY-27ZE

**PARAMETRES:** 3 PLY NON-WOVEN SPUNBOND MELTBLOWN MATERIAL BLUE, WITH ADJUSTABLE NOSE WIRES, ANTI-ALLERGIC AIR IRRIGATION, EASY BREATHABLE, ULTRASONIC 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.*



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20/09/2021

