

# BRBEN TEKSTIL SANAYI VE TICARET A.S.

## EU Declaration of Conformity

REGULATION (EU) 2017/745 Medical Devices Directive Class I establishing technical requirements for medical devices, in effective wording

This is hereby declared that following product are in compliance with the essential health and safety requirements of above Council Directive (s) on the approximation of the laws of the Member State relating to it.

We, BRBEN TESKIL SAN. VE tic. A. S., addressed in 2. OSB 83207 Nolu Cad. No. 2/10 Gaziantep – Sehitkamil / Turkey code SRN

TR-MF-000021341 as manufacturer of the following medical devices:

NAME OF THE PRODUCT	CODE	BRAND	UDI-DI BASIC
FFP2 Filtering half mask white	BR1MSK-001	BRMED	868303626BR1MSK-001SB
Surgical Mask Type IIR Navy Blue	BR3PLY-27	BRMED	868303626BR3PLY-27CT
Surgical Mask Type IIR White	BR3PLY-27	BRMED	868303626BR3PLY-27CT
Surgical Mask Type IIR Blue	BR3PLY-27	BRMED	868303626BR3PLY-27CT
Surgical Mask Type IIR Grey	BR3PLY-27	BRMED	868303626BR3PLY-27CT
Surgical Mask Type IIR Grey Burgundy	BR3PLY-27	BRMED	868303626BR3PLY-27CT
Surgical Mask Type IIR Grey Pink	BR3PLY-27	BRMED	868303626BR3PLY-27CT
Disposable scrub suit/surgical garments set XS	BRSUIT-001HA	BRMED	868303626BRSUIT-001HA / GS1
Disposable scrub suit/surgical garments set S	BRSUIT-001HA	BRMED	868303626BRSUIT-001HA / GS1
Disposable scrub suit/surgical garments set M	BRSUIT-001HA	BRMED	868303626BRSUIT-001HA / GS1
Disposable scrub suit/surgical garments set L	BRSUIT-001HA	BRMED	868303626BRSUIT-001HA / GS1
Disposable scrub suit/surgical garments set XL	BRSUIT-001HA	BRMED	868303626BRSUIT-001HA / GS1
Disposable scrub suit/surgical garments set XXL	BRSUIT-001HA	BRMED	868303626BRSUIT-001HA / GS1
Disposable scrub suit/surgical garments set XXXL	BRSUIT-001HA	BRMED	868303626BRSUIT-001HA / GS1
Disposable scrub suit/surgical garments set 4XL	BRSUIT-001HA	BRMED	868303626BRSUIT-001HA / GS1
Disposable scrub suit/surgical garments set 5XL	BRSUIT-001HA	BRMED	868303626BRSUIT-001HA / GS1
Shoe cover	6113886 OVERSHOES	BRMED	8683036266113886NC / GS1
Laminated boot shoes/overshoe	BRSCVR-001	BRMED	868303626BRSCVR-001CB / GS1
Disposable scrub suit S	BRSUIT-034	BRMED	868303626BRSUIT-034HR / GS1
Disposable scrub suit M	BRSUIT-034	BRMED	868303626BRSUIT-034HR / GS1
Disposable scrub suit L	BRSUIT-034	BRMED	868303626BRSUIT-034HR / GS1
Disposable scrub suit XL	BRSUIT-034	BRMED	868303626BRSUIT-034HR / GS1
Disposable scrub suit XXL	BRSUIT-034	BRMED	868303626BRSUIT-034HR / GS1
Disposable scrub suit XXXL	BRSUIT-034	BRMED	868303626BRSUIT-034HR / GS1
Disposable scrub suit 4XL	BRSUIT-034	BRMED	868303626BRSUIT-034HR / GS1
Disposable scrub suit 5XL	BRSUIT-034	BRMED	868303626BRSUIT-034HR / GS1
Disposable scrub suit S white	WBRUIT034	BRMED	08683036265067 / GS1
Disposable scrub suit M white	WBRUIT034	BRMED	08683036265067 / GS1
Disposable scrub suit L white	WBRUIT034	BRMED	08683036265067 / GS1
Disposable scrub suit XL white	WBRUIT034	BRMED	08683036265067 / GS1
Disposable scrub suit XXL white	WBRUIT034	BRMED	08683036265067 / GS1
Disposable scrub suit XXXL white	WBRUIT034	BRMED	08683036265067 / GS1
Disposable scrub suit 4XL white	WBRUIT034	BRMED	08683036265067 / GS1
Disposable scrub suit 5XL white	WBRUIT034	BRMED	08683036265067 / GS1

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Declare that the above mentioned products are intended for use in diagnostic and health procedures in order to prevent cross-contamination between healthcare professional personnel and patients, risk class I "non-sterile", in accordance with rule 1 of Annex VIII of EU Regulation 2017/745, also declare under its sole responsibility, that such devices:

- comply with the essential requirements and provisions of Regulation (EU) 2017/745 and ss.mm.ii. as per Technical File n. FT 001 CO archived at the holding;
- are manufactured in accordance with the Technical File, which meets the requirements of Annex II and III of the above mentioned Regulation.

Gaziantep, 27/04/2022

This declaration under the responsibility of the Manufacturer



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