

DECLARATION OF CONFORMITY

Company Name: MARKAL TEKSTİL SAN. VE TİC. LTD. ŞTİ.

Address: CUMHURİYET MAH. 14027. SOK. 10/D ONİKİSUBAT
KAHRAMANMARAS / TURKEY

Product Name: Disposable Non-Sterile Surgical Head Cover, Surgical Caps, Boot Cover.

Product Models: Disposable Non-Sterile Gowns - *BLUBss020, BLUBss120, BLUBss130, BLUBss135, BLUBss140*
Disposable Non-Sterile Surgical Head Cover - *BLU-hp01, BLU-hp02, BLU-hp03*
Disposable Non-Sterile Surgical Caps - *BLUScp010, BLUScp011*
Disposable Non-Sterile Boot Cover - *BLU_bc01, BLU_bc02, BLU_bc03*

Brand: MARKAL TEKSTİL

Sterile: No

Classification: According to MDD 93/42/EEC - Annex IX - Class I - Other

Conformity Assessment: According to MDD 93/42/EEC Medical Device Directive Annex V –
Production Quality Assurance

We herewith declare that:

Those above products with CE marking which are manufactured by our company all comply with EU Medical Device Directive **MDD 93/42/EC** (REGULATION (EU) 2017/745), and realize their expected uses. All CE files have been certified by the company, consequently their authenticity has been guaranteed.

STANDARDS APPLIED:

EN ISO 13485 : 2016	EN ISO 10993-5	EN ISO 13795-2	EN ISO 13795-2
EN ISO 15223-1	EN ISO 10993-10	EN ISO 14698-1	93/42/EEC
EN ISO 14971:2019	EN ISO 10993-1	EN ISO 14698-2	

Registry Date: 01.10.2019
Certification Date: 26.08.2021
Expiry Date: 27.05.2026
Place/Date: K.MARAS / 01.11.2021
Authorized Person: Hakan KALINKÜTÜK
Title: General Manager

Signature, Stamp

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