

**ZENMED**TIBBİ CİHAZLAR VE SAĞLIK
ÜRÜN. SAN. VE TİC. LTD. ŞTİ.**EU DECLARATION OF CONFORMITY**

Product Name: NON-STERILE DISPOSABLE BED SHEET. 150X200 cm
GMDN Code: 47783
Legal Manufacturer: ZENMED TIBBİ CİHAZLAR VE SAĞLIK ÜRÜNLERİ SAN. TİC. LTD. ŞTİ.
MAHMUTBEY MAH. 2567. SOK. NO:1/11 BAĞCILAR- İSTANBUL/TURKEY
Reference/Model Number: 20-042-01

ANALYSIS	CRITERIA
TENSILE STRENGTH ISO 29073-3:1996	≥20N (Dry)
BURSTING STRENGTH ISO 13938-1:1999	≥40 kPa (Dry)
WATER PERMEABILITY ISO 811: 2018	≥10 cm H ₂ O
MICROBIAL CLEANLINESS EN ISO 11737-1:2018	≤300 cfu/100cm ²
MICROBIAL RESISTANCE ISO 22612:2005	≤300 cfu/100cm ²
PERFORMANCE TESTED (EN 13795-1:2019)	Standard Performance

CLASSIFICATION: CLASS 1S, RULE 1, ANNEX IX OF MDD 93/42 EEC.

CONFORMITY ASSESSMENT ROUTE: ANNEX V

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF THE COUNCIL DIRECTIVE 93/42/EEC (2007/47/EC) FOR MEDICAL DEVICES, DO NOT CONTAIN HUMAN BLOOD AND DERIVATIVES, DO NOT CONTAIN ANIMAL TISSUE, DO NOT CONTAIN DRUG AND PHARMACEUTICAL COMPONENTS. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

THE PRODUCTS ARE "LATEX FREE"

EU DECLARATION OF CONFORMITY DATE:

14.09.2021

CANER İPİN

Manager

**ZENMED TIBBİ CİHAZLAR
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