

EU DECLARATION OF CONFORMITY

MANUFACTURER

BRBEN TEKSTİL SANAYİ VE TİCARET ANONİM ŞİRKETİ

2.OSB 83207 Cd. No:2/10 Şehitkamil Gaziantep /TURKEY

PRODUCTION DESCRIPTION

Brand Name:BRBEN TEKSTİL

Model: Shoe Cover 6113886, 4046153117444

Disposable Shoe Cover with standart performance to be used to prevent the transmission of infective agents between clinical staff and patients during surgical and other invasive procedures, classified as Medical Device (Calss 1)

The Manufacturer declares on his sole responsibility that the product above is, under conditions of normal use and requirements. The product, a medical device that is intended for single use and solely in accordance with the Manufacturer's instructions.

The Conformity is assessed especially with the following provisions:

- European Regulation (EU) 2017/745 and 93/42 EEC Medical Devices Directive establishing technical requirements for medical devices, in effective wording
- Technical standard EN 13795-1:2009 Surgical clothing and drapes- Requirements and test methods- Part1: Surgical Drapes and gowns
- Other relevant harmonized legislation and standards
- For the assessment of conformity, the following documents were also applied to:
- Results of laboratory test for Microbial Penetration Dry by National Protective Testing LLC
- Results of laboratory test for Microbia Penetration- Wet and Microbial Cleanliness, Bioburden by Ekoteks Laboratuvar ve Gözetim Hizmetleri AŞ
- Results of laboratory tests for Bursting and Tensile Strenghts (wet/dry) by Ekoteks Laboratuvar ve Gözetim Hizmetleri A.Ş.

MARKING, LABELLING

Annex I, 13, of the Medical Devices Directive (93/42/EEC) or Annex I, 23, of the MEDical Device REGulation (EU) 2017/745 specifies the information that should be specified on the packaging in which the Hair Cover is supplied. The informaiton supplied with the product consedering EN ISO 15223-I:2016 and EN 1041:2008+A1:2013.

MEASURES TO ENSURE CONFORMITY

The Manufacturer declares that he has taken all necessary to ensure the conformity of products places on the market with technical documentation and basic requirements for this prodcut.

Adem Altan
General Manager
10/01/2021



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