

EU DECLARATION OF CONFORMITY

MANUFACTURER

YALITKAN PASPAS KAÜÇUK ÜRÜNLERİ A.Ş.

Oruçreis Mah. Tekstil Kent Cad. Tekstil Kent Gd1 Blok No:148 Esenler-İstanbul/TURKEY

PRODUCT DESCRIPTION

Brand Name: AMSTERDAM, Model: YLT003

Surgical Gowns with standard 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 (Class I)

We declare on our sole responsibility that the product above is, under conditions of normal use and conditions defined by the Producer / the Manufacturer, safe and meets all the necessary legal conditions 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 13795-1:2019 Surgical clothing and drapes – Requirements and test methods – Part I: 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 tests for Microbial Penetrations, Microbial Cleanliness (Bioburden), Bursting and Tensile Strengths 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 surgical gown is supplied. The information supplied with the product considering EN ISO 15223-1:2016 and EN 1041:2008+A1:2013

MEASURES TO ENSURE CONFORMITY

We declare that we have taken all necessary measures to ensure the conformity of products placed on the market with technical documentation and basic requirements for this type of product.

 **YALITKAN PASPAS**
KAÜÇUK ÜRÜNLERİ A.Ş.
Oruç Reis Mah. Tekstil Kent Cad. Tekstil Kent Gd1
No:10 AE Daire No: 220 Esenler / İSTANBUL
Aşağıları V.D.1: 9330929051 - Sicil No: 223853-5
Mersis No: 0933092605100001
Engin Özavcı

General Manager

09/03/2021

