

EU DECLARATION OF CONFORMITY

MANUFACTURER

GİYİNİŞ TEKSTİL ANONİM ŞİRKETİ

Hürriyet Mahallesi Çilingir Sokak E1 Blok No:3/6A Büyükkçekmece İSTANBUL / TURKEY

PRODUCT DESCRIPTION

Brand Name: Onsteril

Model: OLI-2022

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)

The Manufacturer declares on his 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 1: 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 Penetration - Wet and Microbial Cleanliness, Bioburden by Ekoteks Laboratuvar ve Gözetim Hizmetleri A.Ş.
- Results of laboratory tests for Bursting and Tensile Strengths (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 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

The Manufacturer declares that he has 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.

General Manager
07/07/2020



ATTESTATION OF CONFORMITY**Certificate No: MDD-175**

In conformance to the European Economic Commission 93/42/EEC Medical Devices Directive on harmonisation of laws, regulations and administrative documentation of Member States on Medical Devices and European Economic Commission directive 93/68/EEC amending Medical Devices Directive dated 22 July 1993,

the products manufactured by

GIYINIŞ TEKSTİL ANONİM ŞİRKETİ

at the following address

Hürriyet Mahallesi Çilingir Sokak E1 Blok No:3/6A Büyükçekmece İSTANBUL / TURKEY

EN 13795-1:2019 Surgical Clothing and Drapes - Requirements and Test Methods - Part 1: Surgical Drapes and Gowns**Brand Name:** Onsteril**Model:** OLI-2022

(Standard Performance) are tested according to the following initial type tests by the manufacturer

For the assessment of conformity, the following documents were also reviewed:

Laboratory test results for Microbial Penetration (wet/dry), Bioburden,

Bursting and Tensile Strengths (wet/dry)

UNIVERSAL CERTIFICATION has evaluated production, design, intended use, risk evaluation according to safety purpose, product itself and add-on components (if exists) and product technical drawings of the surgical gowns manufactured and designed for use to prevent the transmission of infective agents between clinical staff and patients during surgical and other invasive procedures. With this certificate, it is approved that the product fulfils all essential requirements and the related rules of 93/42/EEC Medical Devices Directive (MDD) Class I are applied. The information on the packaging for the above listed products covers the necessary information stated in Annex I, §13, of the Medical Devices Directive (93/42/EEC) or Annex I, §23, of the Medical Device Regulation (EU) 2017/745. This information includes; performance level and other relevant information given in EN ISO 15223-1:2016 and EN 1041:2008+A1:2013. It is considered to be suitable to attach a CE mark, as seen below, on your products in accordance with the information given in this certificate with publishing an EU Declaration of Conformity.

This certificate is issued on 07/07/2020 and valid until 06/07/2021 with the conditions that no change has been made with the product references and no change in the production process or not suspended or withdrawn for any reason.

İSTANBUL -07/07/2020



Suat KACMAZ

UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR Code