

# EU DECLARATION OF CONFORMITY

## MANUFACTURER

**İBİŞLER TEKSTİL SANAYİ VE DIŞ TİCARET ANONİM ŞİRKETİ**  
Gürsel Mahallesi Tümleç Caddesi No:1 Kağıthane İSTANBUL / TURKEY

## PRODUCT DESCRIPTION

**Brand Name : A&Z MED, Model: OLI – 2023**

This declaration of conformity is drawn up under the manufacturer's own authority and responsibility. 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:
- The notified body Universal Certification and Surveillance Service Trade Ltd. Co., Necip Fazıl Bulvarı Keyap Sitesi E2 Blok No: 44/84 Yukarı Dudullu, Ümraniye-İstanbul, Turkey
- Results of laboratory tests for Microbial Penetration (Dry/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.

LOT 2020-53



**Olgun İBİŞ**

Chief Executive Officer

08.05.2020 İstanbul

**İBİŞLER TEKSTİL SAN VE DIŞ TİC A.Ş.**

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