



# EUROTECH CERTIFICATION

## *Conformity Certificate*

**No. 3125 MDD 081/EU**

This certificate applies for the product that specifications have detailed

**Disposable Surgical / Medical Gowns ( Brand Name: FULLSET )**

And manufactured by the below company:

**FULSET TEKSTIL OZEL SAG. HIZ. SAG. MAL. INS. TUR. SAN. VE TIC. LTD. STI.**

**Veysel Karani Mh. 4. Veysel Sk. No:44/6 Osmangazi/BURSA/TURKEY**

The relevant directives and related standards declared by the company are as follows:

**93/42/EEC and 2007/47/EC - Medical device directive**

**EN 13795-1:2019 - Surgical clothing and drapes - Requirements and test methods - Part 1: Surgical drapes and gowns**

For the assessment of the results of laboratory tests by Ekoteks Laboratuvar Testing  
(Acc. No: AB-0583-T), dated as 22.02.2021, with report no 21005626

EUROTECH, 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 Disposable Surgical / Medical 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 packing for the above listed products covers the necessary information stated in Annex I, §13, of the Medical Device 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 15223-1:2021 and EN 1041:2008+A1:2013.

It is considered to be suitable to attach a CE mark, as seen below, on the products in accordance with the information given in this certificate with publishing an EU Declaration Of Conformity.



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