

DECLARATION OF CONFORMITY

In conformance to 93/42/EEC MDD on harmonization of laws, regulations, and administrative documentation of Member States of Medical Devices and 93/68/EEC amending MDD dated 22 July 1993 the products manufactured by

Name and address of the manufacturer

SANDEKS İTHALAT İHRACAT TİC. VE Y.İCİ - Y.İCİ NAK. LTD. STİ.

Head Office: Yaylacık Mah. 37.(470) Sk. No: 9 /1 Nilüfer/ Bursa
Production Address : İstasyon Mh. Hukümet Cd. Gabrali Lojman Sitesi
No: 31/1/1 Cerkezköy - Tekirdağ / Turkey

Products

DISPOSABLE SURGICAL GOWN

Brand Name / Model

SANDEKS İTHALAT İHRACAT TİC. VE Y.İCİ-Y.İCİ NAK. LTD. STİ.

Harmonized standards

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

Technical File

With the no 2020156790 have been realized for the marking process.

Test Report

2020156790

Tested according to the following initial type tests by the manufacturer.
Microbial Penetration, Bioburden, Tensile and Bursting Strengths (Dry and Wet)

UKS has evaluated production, design, product, intended use, risk evaluation, product technical file. With this certificate, It is approved that the products fulfill all essential requirements and related rules of 93/42 EEC MDD Class I are applied. It is considered to be attached a CE mark on products with publishing a EU Declaration of Conformity

Certificate No : CED-0019
Certificate Date : 09.06.2020
Certificate Exp. Date : 08.06.2021



General Manager

