

EU DECLARATION OF CONFORMITY

in conformance to the European Economic Commission 93/42/EEC Medical Devices Directive on harmonization of laws

This declaration of conformity is issued under the sole responsibility of PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ. We hereby declare that the medical device specified below meet the provision of the Regulation (EU) 93/42/EEC for medical devices.

MANUFACTURER: PODİMA MEDİKAL VE TEKSTİL SAN. TİC. LTD. ŞTİ.

YUKARI DUDULLU MAH. BAYRAK CAD. NO: 30 / 130 ÜMRANİYE

34775 İSTANBUL / TURKEY

DESCRIPTION: DISPOSABLE GOWN

SPECIFICATION: STERILE AND NON-STERILE

ITEM NUMBERS: SV-180 - SV-181 - SV-182 - SV-183 - SV-184 - SV-185 - SV-186 -

SV-187 - SV-188 - SV-189

TRADE MARK:

SUVICOM

DIRECTIVES: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993

concerning medical devices (MDD/93/42EEC). Amended by

DIRECTIVE 2007/47/EC of 5 September 2007.

RELATED STANDARTS:

Classification (MDD, Annex IX): Class I, Rule I

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.

Authorized person and Position: Mehmet Ali Özkan / Owner

Issue Date and Place: 06.04.2021/Istanbul, Turkey



Sign - Stamp
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