UNIVERSAL CERTIFICATION

ATTESTATION OF CONFORMITY

Certificate No: MDD-252

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 Commission directive 2007/47/EC amending Medical Devices Directive dated 05 September 2007,

the products manufactured for

CARINE EUROPE GMBH

at the following address
Ammannstrasse No:12 86167 Augsburg / GERMANY

by the following manufacturer

AYDAĞ TEDAVİ ve SAĞLIK HİZMETLERİ SAN. ve TİC. A.Ş
Orta Mah. Menderes Cad. No:7/3 K1 Bayrampaşa İstanbul TURKEY

EN 13795-1:2019 Surgical Clothing and Drapes - Requirements and Test Methods - Part 1: Surgical Drapes and Gowns

Brand Name: Carine Medical
Model: CRM - SGA
(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 06/09/2020 and valid until 05/09/2021 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that no change has been made with the product references and no change in the production process or not suspended or withdrawn for any reason.

ISTANBUL – 06/09/2020

CE

Suat KAÇMAZ
UNIVERSAL CERTIFICATION
Director

Verify the validity with the QR Code

This certificate will be in the absence of any changes in standard and legal terms, and with the surveillance audits to be concuted annually following the surveillance audits, updating the publicationdate without changing the certificate number.