



EC DECLARATION OF CONFORMITY

Manufacturer

DARK BLUE MEDICAL DEVICES LTD.

Address

BULGARIA, NIKAPOL, STREET RAKOVSKI NR.2

Phone

359 88 807 67 95

E-mail

darkblue.bg@gmail.com

Product Name

SURGICAL FACE MASK (DISPOSABLE)

ASTM F2100-11 Classification / Level 3 Face Mask

EN 14683 Classification / Ultrasonic (Seamless) Production Face Mask

Types of Product

Type I / II / IIR

TWO-LAYER, WITH LACED

TWO-LAYER, WITH EARLOOPS

THREE-LAYER, WITH LACED

THREE-LAYER, WITH EARLOOPS

Statement

Here, we declare that the products listed above are manufactured under our own responsibility as a Manufacturer, Distributor / Representative by the EU, in accordance with the 93/42/EEC Medical Device Directive and regulations.

Directives and Regulations

93/42/EEC Medical Device Directive

Product Commercial Brand



Harmonized Standards

93/42/EEC- Medical Devices Regulation / Class I (Non Sterile)

TS EN 14683+AC Medical face masks - Requirements and test methods-Type II / IIR

ISO 9001:2015 Quality Management System

ISO 13485:2016 Quality Management System for Medical Devices

Certificate No: 2020-13186

Certificate Date: 27.08.2020

Certificate Expiration Date: 27.08.2021

Accredited System Certification Approval



European
Commission

IFC Global Certification Inspection & Training Services GmbH

Hohenzollernring 50 / 50672 Köln / Germany

info@ifcglobal.de

CERTIFICATE / ЗЕРТИФИКАТ / СВИДЕТЕЛЬСТВО / СЕРТИФИКАТ / CERTIFICATO / CERTIFICA