NVA QUALITY CERTIFICATION

NVA QUALITY CERTIFICATION

DEXXON MEDICAL

CE DECLARATION OF CONFORMITY

Manufacturer : **DEXXON ENERJİ SANAYİ VE TİCARET A.Ş.**
Address : İstanbul Vizyon Park Ofis Blokları Yeni Bosna Merkez Mah.
29 Ekim Cad. No:3 Plaza: 1 Kat: 8 No: 84 Bahcelievler / Istanbul / Turkey

In our delivered version, we declare that the product described below complies with the essential safety and health equirements of the **Medical Devices Directive 93/42 /EEC- General Product Safety Directive 2001/95/EEC** regulations as circulating by us. This declaration will cease to be valid if the product specified below is replaced.

Product Description	: DISPOSABLE LAMINATED MEDICAL GOWN
Product Model No	: DXNMD-DNSMLG- 09
Brand	: DEXXON MEDICAL
Related Directive	: 93/42 /EEC Medical Device Directive
Applied Standard	: EN 13795-1:2019; ANSI /AAMI PB 70 ANNEX 1: SURGICAL CLOTHING AND DRAPES
Classification	: Class I ,Non-Sterile
Type	: Level III
Certificate No	: NVA-EC-21022306
Release Date	: 23.02.2021
Validity Date	: 23.02.2022

For the assessment of confirmity, the following documents were also applied to:

Required Tests

Microbiological Tests

Resistance to bacterial penetration (wet)	: EN ISO 22610: 2006
Microbial Cleanliness (Bioburden)	: EN ISO 11737-1:2018
Invitro Cytotoxicity Test	: EN ISO 10993-5, EN ISO 10993-12

Physical Properties Tests

Water Permeability	: ISO 811:2018
Burst Strength (wet/ dry)	: EN ISO 13938-1:1999
Tensile Strength (wet/ dry)	: EN ISO 29073-3:1996
Water Resistance-Impact Penetration	: AATCC 42:2017
Water Resistance: Hydrostatic Pressure	: AATCC 127: 2017

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.
This information includes; reference to EN13795:1:2009 standard, type of gown and other relevant information given in EN ISO 15223-1:2016 and EN 1041:2008 +A1:2013

We declare that the applicable requirements of the product groups described above Medical Device Directive 93/42 AT have beer fullfilled and are responsible.

The product groups described above have been checked by NVA Quality Certification based on internal production controls an as evaluated production, design, intended use, risk evaluation according to safety purpose, product itself and add-on component nd product technical drawings of the medical face masks manufactured and designed for use during the medical operations o imilar medical situations with same requirements which require restriction of infectious materials to be spread to patients.

DEXXON ENERJİ SANAYİ VE TİCARET A.Ş. declares that the 93/42/EEC Medical Devices Directive has fulfilled the applicabl requirements and responsibility has been taken for the above-described product groups. The product groups described above hav been checked by NVA Quality Certification, depending on the relevant technical file and internal production controls

DECLARATIVE
ON ENERJİ SANAYİ VE TİCARET A.Ş.
DEXXON ENERJİ SANAYİ VE TİCARET A.Ş.

APPROVAL
NVA QUALITY CERTIFICATION

NVA KALİTE TEST ÖLÇÜM HİZMETLERİ EĞİTİM VE BELGELENDİRME TİC. LTD. ŞTİ.
Beylikdüzü OSB Mahallesi 3. Cadde HGS İnşaat Corner Office Apt. No: 8/55 Beylikdüzü / İSTANBUL / TURKEY
Tel: +90 212 855 58 98 www.nvabelge.com info@nvabelge.com