NVA QUALITY CERTIFICATION

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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 Bahçelievler / Istanbul / Turkey

In our delivered version, we declare that the product described below complies with the essential safety and health requirements 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 SMMS PE LAMINATED REINFORCED SURGICAL GOWN -STERILE
Product Brand	: DEXXON MEDICAL
Product Model No	: DXNMD-DSLRSG12
Related Directive	: 93/42 /EEC Medical Device Directive
Applied Standard	: EN 13795-1:2019 **Surgical clothing and drapes - Requirements and test methods – Part 1: Surgical drapes and gowns**
Classification	: Class IS , Sterile
Level	: LEVEL 3
Certificate No	: NVA-EC-21052604
Release Date	: 26.05.2021
Validity Date	: 26.05.2022

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
Resistance to microbial penetration (dry)	: EN ISO 22612: 2005
Microbial Cleanliness (Bioburden)	: EN ISO 11737-1:2018
Sterilite Test	: EN ISO 11737-2
Invitro Cytotoxicity Test	: EN ISO 10993-5, EN ISO 10993-12

Physical Properties Tests

Water Resistance (Liquid penetration)	: ISO 811 : 2018
Bursting Strength (wet/ dry)	: EN ISO 13938-1:1999
Tensile Strength (wet/ dry)	: EN ISO 29073-3:1996

ANSI /AAMI PB 70 :2012
Liquid barrier performance and classi cation of protective apparel and surgical gowns

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 IS 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 been fullfilled and are responsible.
The product groups described above have been checked by NVA Quality System Certification based on internal production controls and has evaluated production, design, intended use, risk evaluation according to safety purpose, product itself and add-on components and product technical drawings of the medical face masks manufactured and designed for use during the medical operations or similar 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 applicable equirements and responsibility has been taken for the above-described disposable non-sterile surgical mob caps. The product roups described above have been checked by NVA Quality Certification, depending on the relevant technical file and internal roduction controls.

DECLARATIVE
DEXXON ENERJİ SANAYİ VE TİCARET A.Ş.

APPROVAL
NVA QUALITY CERTIFICATION

Manufacturer : DEXXON ENERJİ SANAYİ VE TİCARET A.Ş. www.dexxonn.com.tr
NVA KALİTE TEST ÖLÇÜM HİZMETLERİ EĞİTİM VE BELGELENDİRME TİC. LTD. ŞTİ.
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