

# NVA QUALITY CERTIFICATION



## 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 / İstanbul / 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 STANDARD SURGICAL GOWNS SMMS-STERILE  
**Product Brand** : DEXXON MEDICAL  
**Product Model No** : DXNMD-DSSG-SMMS05  
**Related Directive** : 93/42 /EEC Medical Device Directive  
**Applied Standard** : EN 13795-1:2019 SURGICAL CLOTHING AND DRAPES  
ANNEX 1 : SURGICAL CLOTHING AND DRAPES  
**Classification** : Class IS , Sterile  
**Certificate No** : NVA-EC-21052602  
**Release Date** : 26.05.2021  
**Validity Date** : 26.05.2022

For the assessment of conformity ,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

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 fulfilled and are responsible.

The product groups described above have been checked by NVA Quality 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 requirements and responsibility has been taken for the above-described disposable non-sterile surgical mob caps. The product groups described above have been checked by NVA Quality Certification, depending on the relevant technical file and internal reduction controls.

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

**APPROVA**  
NVA QUALITY CERTIFICATION



Manufacturer : DEXXON ENERJİ SANAYİ VE TİCARET A.Ş. [www.dexxon.com.tr](http://www.dexxon.com.tr)

NVA KALİTE TEST ÖLÇÜM HİZMETLERİ EĞİTİM VE BELGELENDİRME TİC. LTD. ŞTİ.  
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