

# 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 SURGICAL GOWN, SMS STERILE  
**Product Brand** : DEXXON MEDICAL  
**Product Model No** : DXNMD-DSSG18  
**Material** : PP SMS  
**Applicable Directives** : MEDICAL DEVICES DIRECTIVE 93/42 / EEC ANNEX -VII  
**Applicable Harmonized Standards** : EN 13795-1: 2009  
**Classification** : Class 1S , Sterile

**Related Directive** : 93/42 /EEC Medical Device Directive  
**Applied Standards** :  
EN 13795-1:2009 Surgical Clothing and Drapes -Requirements and Test Methods Part 1: Surgical Drapes and Gowns

**Certificate No** : NVA-EC-21061108  
**Release Date** : 11.06.2021  
**Validity Date** : 11.06.2022

**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 Permeability : ISO 811 : 2018  
Burst 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 Device Directive (MDD) Class 1S are applied. This information includes reference to EN13795:1 standard, type of surgical drapes other relevant information given in EN ISO 15223-1:2016 and EN 1041:2008 +A1:2013

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 production controls.

**DECLARATIVE**  
DEXXON ENERJİ SANAYİ VE TİCARET A.Ş.  
ENERJİ SANAYİ VE TİCARET A.Ş.  
Yeni Bosna V.D.: 325053419

**APPROVAL**  
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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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