



## 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 PE LAMINATED EXTRA REINFORCED SURGICAL GOWN, STERILE  
**Product Brand** : DEXXON MEDICAL  
**Product Model No** : DXNMD- DSLERSG16  
**Material** : PP SMMS, SSMMMS  
**Applicable Directives** : MEDICAL DEVICES DIRECTIVE 93/42 / EEC ANNEX -VII  
**Applicable Harmonized Standards** : EN 13795-1: 2009, EN 13795-2: 2009 ; AAMI PB70  
**Classification** : Class IS , Sterile  
**AAMI Protection** : Level 3, Moderate Protection  
**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  
EN 13795-2:2009 Surgical Clothing and Drapes - Requirements and Test Methods  
Part 2: Surgical Drapes, Gowns and Clean air suits

**Certificate No** :  
**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  
Blood penetration : ISO 16603:2004  
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

#### ANSI /AAMI PB 70 :2012

#### Liquid barrier performance and classification 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 and EN 13795:2 standard, type of surgical drapes, gowns and clean air suits 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 product groups.

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 Mah. 29 Ekim Cad. No:3 Plaza 1 Kat: 8 No: 84 Bahçelievler / İstanbul / Turkey  
V.D.: 3250527

**APPROVAL**  
NVA QUALITY CERTIFICATION

