

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 Bahcelievler / 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
Product Brand : DEXXON MEDICAL
Product Model No : DXNMD- DNSLERSG15
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 1 , Non-Sterile
AAMI Protection : Level 3, Moderate Protection
Related Directive Applied Standards : 93/42 /EEC Medical Device Directive
: 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 : 21061105
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
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 I are applied. This information includes; reference to EN13795-1 and EN 13795:2 standard, type of surgical drapes, gowns and clean suits other relevant information given in EN ISO 15223-1:2016 and EN 1041:2008 +A1:2013

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

DEXXON ENERJİ SANAYİ VE TİCARET A.Ş. declares that the 93/42/EEC Medical Devices Directive has fulfilled the applicab. 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 an internal production controls.

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

APPROVAL
NVA QUALITY CERTIFICATION



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