NVA
QUALITY CERTIFICATION

CE

DEXXON® MEDICAL

CE DECLARATION OF CONFORMITY

Manufacturer : **DEXXON ENERJİ SANAYİ VE TİCARET A.Ş.**
Address : Mahmutbey Mah., Soğuksu Cad., No:16 Kat: 9 Trade Tower
Bağcılar / İSTANBUL / TURKEY

The manufacturer declares under his sole responsibility that:

The medical product listed below

Product Name : Surgical Gown
Product Code : Disposable Non-Sterile
Material : SMMS
Article No : DXNMD-DNSMG SMMS08
Manufacturer : DEXXON ENERJİ SANAYİ VE TİCARET A.Ş.
Brand Name : DEXXON MEDICAL
Pruduct Class : Class I, According to Rule I, Annex VIII, Chapter III of EU Medical Device Regulation (EU) 2017/745

*We hereby declare that the product described above in our delivered version complies with the **Medical Device Regulation (EU) MDR 2017/745** as put into circulatin by us.*
*The medical devices had been classified as a **Class I Medical Device** in accordance with Annex I of Directive (EU) 2017/745 and it complies with the following applicable harmonized standards:*
Technical documentation that meets the requirements of the above-mentioned directive, Annex II and III, is available as proof.
This Declaration of Conformity covers the medical device as specified in the product list belonging to this declaration
*The product identified above complies with the general safety and performance requirements of Regulation **(EU) 2017/745** by meeting the following standarts:*

Applied Standard : EN 13795-1:2009 Surgical Clothing and Drapes -Requirements and Test Methods
Applicable Harmonised Standards : EN 13795-1: 2009, EN ISO 13485: 2016
Conformity Assessment Procedure : Annex IX of Regulation (EU) 2017/745
Risk of the Device : The Medical Device has been assigned to Class I
Classification /Rule : Rule 1 according to Annex VIII, Medical Device Regulation (EU) 2017/745
Classification Name : Disposable Non –Sterile Surgical Gown
Certificate No : NVA-EC-21050501
Release Date : 07.07.2022
Validity Date : 07.07.2023

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
Microbial Cleanliness (Bioburden) : EN ISO 11737-1:2018

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 2017/745 Medical Devices Regulation (MDR) according to Annex VIII, Class I are applied.
As a manufacturer, we declare that the product concerned has been designed and manufactured under a quality management system acording to ANNEX IX Medical Device Regulation (EU) 2017/745.

*The product groups described above have been verified by **NVA Quality Certification** on the basis of internal production controls and have assessed the production, design, intended use, risk assessment against the safety objective, the product itself and additional components and technical drawings of the product.*

***DEXXON ENERJİ SANAYİ VE TİCARET A.Ş.** declares that the Medical Device Regulation 2017/745 has met the applicable requirements and responsibility has been taken for the product groups described above.*
This declaration will cease to be valid if the product specified above is replaced.

DECLARATIVE
DEXXON ENERJİ SANAYİ VE TİCARET A.Ş.

APPROVAL
NVA QUALITY CERTIFICATION

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