NVA QUALITY CERTIFICATION

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CE

DEXXON® MEDICAL

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 / Istanbul / Turkey

In our delivered version, we declare that the product described below complies with the essential safety and health equirements 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 Name	: Disposable Surgical Scrub Suits (Shirt and Pants)
Brand Name	: DEXXON MEDICAL
Model	: DXNMD-DNSSS14
Material	: PP, SMS
Applicable Directives	: MEDICAL DEVICES DIRECTIVE 93/42 / EEC ANNEX –VII
Applied Standard	: EN 13795-1:2009 Surgical Clothing and Drapes -Requirements and Test Methods
Applicable Harmonized Standards	: EN 13795-1: 2009, EN ISO 13485: 2016
Classification	: The product is subject to Medical Devices Regulation Class 1
Certificate No	: 21061104
Release Date	: 11.06.2021
Validity Date	: 11.06.2022

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 93/42/EEC Medic 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 IS 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 require 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 production controls.

DECLARATIVE
DEXXON ENERJİ SANAYİ VE TİCARET A.Ş.

DEXXON ENERJİ SANAYİ VE TİCARET A.Ş.

APPROVAL
NVA QUALITY CERTIFICATION

NVA KALİTE TEST ÖLÇÜM HİZMETLERİ EĞİTİM VE BELGELENDİRME TİC. LTD. ŞTİ.
Beylikdüzü OSB Mahallesi 3. Cadde HGS İnşaat Corner Office Apt. No: 8/55 Beylikdüzü / İSTANBUL / TURKEY
Tel: +90 212 855 58 98 www.nvabelge.com info@nvabelge.com

CE

DEXXON MEDICAL

EU 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 Istanbul / Turkey

EN 13795-1:2009 Surgical Clothing and Drapes -Requirements and Test Methods

Product Name	: Disposable Surgical Scrub Suits (Shirt and Pants)
Brand Name	: DEXXON MEDICAL
Model	: DXNMD-DNSSS14
Material	: PP, SMS
Applicable Directives	: MEDICAL DEVICES DIRECTIVE 93/42 / EEC ANNEX -VII
Applicable Harmonized Standards	: EN 13795-1: 2009, EN ISO 13485: 2016
Classification	: The product is subject to Medical Devices Regulation Class 1

(Standard Performance) are tested according to EN 13795-1 and EN ISO 13485:2016 tests by manufacturer.

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

DEXXON ENERJİ SANAYİ VE TİCARET A.Ş has evaluated production, design,intended use ;risk evaluation according to safety purpose, product itself and add-on components (if exists) and product technical drawing ıf the surgical gowns manufactured and designed for use the prevent the transmission of ineffective agents between clinical staff and patients during surgical and other invasive procedures.
With this declaration it is approved that the product fulfills all essential requirements and the related rules of 93/42 /EEC Medical Devices (MDD) Class I are applied. The information on the packaging for above listed products covers the necessary information stated in Annex I, 13 of the Medical Devices Directive (93/42 /EEC) or Annex 1,23 of the Medical Device Regulation (EU) 2017/745 .

This information includes; performance level and other relevant information given in EN ISO 15223-1: 2016 and EN 1041:2008+A1:2013. It is considered to be suitable to attach a CE mark; as seen below, on you products in accordance with the information given in this declaration with publishing an EU Declaration of Conformity.

DECLARATIVE

DEXXON ENERJİ SANAYİ VE TİCARET A.Ş

Signed by: Murat KOÇ
President
Date : June 11 , 2021