



CE DECLARATION OF CONFORMITY

Manufacturer : DEXXON ENERJİ SANAYİ VE TİCARET A.Ş.
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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 STANDARD SURGICAL GOWNS SS-STERILE
Product Brand : DEXXON MEDICAL
Product Model No : DXNMD-DSMG-SS04
Related Directive : 93/42 /EEC Medical Device Directive
Applied Standard : EN 13795-1:2019 SURGICAL CLOTHING AND DRAPES
ANNEX 1 : SURGICAL CLOTHING AND DRAPES
Classification : Class IS , Sterile
Certificate No : NVA-EC-21052601
Release Date : 26.05.2021
Validity Date : 26.05.2022

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
Sterility Test : EN ISO 11737-2
Invitro Cytotoxicity Test : EN ISO 10993-5, EN ISO 10993-12

Physical Properties Tests

Water Resistance (Liquid penetration) : ISO 811 : 2018
Bursting 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 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 ISO 15223-1:2016 and EN 1041:2008 +A1:2013

We declare that the applicable requirements of the product groups described above Medical Device Directive 93/42 AT have been fulfilled and are responsible.

The product groups described above have been checked by NVA Quality Certification based on internal production controls and has evaluated production, design, intended use, risk evaluation according to safety purpose, product itself and add-on components and product technical drawings of the medical face masks manufactured and designed for use during the medical operations or similar medical situations with same requirements which require restriction of infectious materials to be spread to patients.

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.

APPROVAL
NVA QUALITY CERTIFICATION



Manufacturer : DEXXON ENERJİ SANAYİ VE TİCARET A.Ş. www.dexxon.com.tr
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