



**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 / 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 NON-STERILE MEDICAL FACE MASK
Product Model No	: DXNMD-DNSMFM-03
Brand	: DEXXON MEDICAL
Related Directive	: 93/42/EEC Medical Device Directive
Applied Standard	: EN 14683:2019 +AC:2019; 2001/95 /EEC
Classification	: Class I, Non-Sterile
Type	: Type II R
Certificate No	: NVA-EC-21022303
Release Date	: 23.02.2021
Validity Date	: 23.02.2022

For the assessment of conformity, the following documents were also applied to:

Required Tests

Microbiological Tests:

Bacterial Filtration Efficiency (BFE)	: EN 14683 : 2019: AC:2019 Medical Face Masks, Requirements and Test Methods
Microbial Cleanliness (Bioburden)	: ISO 1173-1:2018
Splash Resistance	: EN 14683:2019 : AC:2019 (Clause 5.2.4), EN ISO 22609:2004
Invitro Cytotoxicity Test	: EN ISO 10993-5, EN ISO 10993-12

Physical Properties:

Breathability (Differential Pressure)	: EN 14683: 2019 : AC: 2019 EK-C
---------------------------------------	----------------------------------

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, Type II R are applied.

This information includes; reference to EN14683 standard, type of mask and other relevant information given in EN ISO 15223-1:2016

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 as evaluated production, design, intended use, risk evaluation according to safety purpose, product itself and add-on component 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 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.

DEXXON ENERJİ SANAYİ VE TİCARET A.Ş.

Yeni Bosna V.D.: 325093271

APPROVAL

NVA QUALITY CERTIFICATION

Signature

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

