

NVA QUALITY CERTIFICATION



EC 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 11 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 : CORPSE BAG
Product Brand : DEXXON MEDICAL
Product Model No : DXNMD-CB019
Product Material : PE (Polyethylene), PP (Polypropylene), PEVA (Polyethylene-co-vinyl acetate), PVC Vinyl
Classifications : Class I

Applicable EC Directives : GENERAL PRODUCT SAFETY DIRECTIVE 2001/95/EEC
MEDICAL DEVICES DIRECTIVE 93/42/EEC

Applicable Harmonized Standards : EN ISO 13485:2016
Related Directive : 93/42 /EEC Medical Device Directive

Certificate Number : NVA-EC-21072604
Certificate Issue Date : 26.07.2021
Certificate Validity Date : 26.07.2022

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.

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.
Yeni Bosna V.D.: 3250532710



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

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

