



CE DECLARATION OF CONFORMITY

Manufacturer	DEXXON ENERJİ SANAYİ VE TİCARET A.Ş.
Address	Istanbul Vizyon Park Ofis Binaları Yeni Bosna Merkez Mah. 29 Ekim Cad. No:3 Plaza: 1 Kat: 8 No: 84 Bahçelievler / Istanbul / Turkey
Product Description	EMERGENCY RESCUE BLANKET
Article No	DXNMD DRBLO1
Manufacturer	DEXXON ENERJİ SANAYİ VE TİCARET A.Ş.
Brand Name	DEXXON MEDICAL
Product Class	Class I, Rule I Medical Device Regulation (EU) 2017/745 Annex VIII Classification According to Directive 93/42/EEC Annex IX
Product Type	Disposable, Non Sterile
Duration of Use	Short Term According to Directive 93/42 /EEC Annex IX

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 circulation 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 standards:

Conformity Assessment Route	Medical Device Regulation 2017/ 745 Annex VIII
Applicable Harmonised Standards	EN ISO 13485:2016, EN ISO 14791:2012, EN ISO 15223-1:2016
Rule	Rule 1, Annex VIII, Regulation (EU) 2017/745
Conformity Assessment Procedure	Annex II and Annex III of Regulation (EU) 2017/745
Risk of the Device	The Medical Device has been assigned to Class I,
Classification	Rule 1 according to Annex VIII, Medical Device Regulation (EU) 2017/745
Certificate No	NVA-EC-22030702
Release Date	07.03.2022
Validity Date	07.03.2023

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.

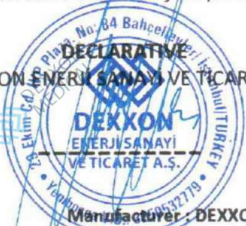
As a manufacturer, we declare that the product concerned has been designed and manufactured under a quality management system according to ANNEX IX Medical Device Regulation (EU) 2017/745

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



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