NVA
QUALITY CERTIFICATION

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 / İstanbul / Turkey

Product Description	EMERGENCY RESCUE BLANKET
Article No	DXNMD DRBLO1
Manufacturer	DEXXON ENERJİ SANAYİ VE TİCARET A.Ş.
Brand Name	DEXXON MEDICAL
Pruduct 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 Therm 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 circulatin 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 standarts:*

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 Classification	The Medical Device has been assigned to Class I, 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 acording 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

DEXXON ENERJİ SANAYİ VE TİCARET A.Ş.