Declaration of Conformity

EU Declaration of Conformity

Manufacturer	**DEXXON ENERJİ SAN. VE TİC. A.Ş**
Adress	YENİBOSNA MERKEZ MAH., 29 EKİM CAD., İSTANBUL VİZYON PARK OFİS BLOKLARI, PLAZA: 1 FLOOR : 8 BAHÇELİEVLER / İSTANBUL / TURKEY
Medical Device Name	Disposable Rescue Blanket
Article No	DXNMD DRBL01
Pruduct Class	Class I , Rule I Medical Device Regulation (EU) 2017/745 Annex VIII
Product Type	Non Sterile
Brand Name	DEXXON MEDICAL
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.*

Technical documentation that meets the requirements of the above-mentioned directive, Annex II and III, is available as proof.

*The above mentioned declaration of conformity is exclusively under the responsibility of **DEXXON ENERJİ SAN. VE TİC. A.Ş***

This declaration will cease to be valid if the product specified above is replaced.

Conformity Assessment Route	Medical Device Regulation 2017/ 745 Annex VIII
Applicable Harmonised Standards	EN ISO 13485:2016 , EN ISO 14791:2020, EN ISO 15223-1:2016,
Rule	Rule 1, Annex VIII, Regulation (EU) 2017/745
Conformity Assessment Procedure	Annex II and III of Regulation (EU) 2017/745
Risk of the Device	The Medical Device has been assigned to Class I ,
Date	07.03.2022

07.03.2022
Murat Koç
General Manager

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