

EU Declaration of Conformity

Manufacturer	DEXXON ENERJİ SANAYİ VE TİCARET A.Ş.
Adress	Mahmutbey Mah., Soğuksu Cad., No:16 Kat: 9 Trade Tower Bağcılar / İSTANBUL
Medical Device Name	Disposable Non-Sterile Surgical SMS Gown
Article No	DXNMD-DNSMG SMS07
Classification	Class I , According to Rule I , Annex VIII , Chapter III of EU Medical Device Regulation (EU) 2017/745
Brand Name	DEXXON MEDICAL

We hereby declare that the above mentioned medical devices meet the provisions of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices.

*This EU Declaration of Conformity is issued under sole responsibility of **DEXXON ENERJİ SANAYİ VE TİCARET A.Ş.** and according to Annex IV of the referred Regulation.*

This DoC is valid for the products mentioned on the addendum. Technical documentation that meets the requirements of the above-mentioned directive, Annex II and III, is available as proof. This declaration will cease to be valid if the product specified above is replaced.

Product category:	Disposable Non-Sterile Surgical Gown
Conformity Assessment Route	Annex II, Annex III Medical Device Regulation (EU 2017/ 745)
Applicable Harmonised Standards	EN 13795-1: 2019 , EN ISO 13485:2016 , EN ISO 14791:2012, EN ISO 10993-1:2018, EN ISO 10993-5:2009 , EN ISO 10993-10 :2013, EN 62366-1:2015, EN ISO 15223-1:2016, EN 1041:2008+A1:2013
Rule	Rule 1, Annex VIII, Regulation (EU) 2017/745
Conformity Assessment Procedure	Annex IX of Regulation (EU) 2017/745
Risk of the Device	The Medical Device has been assigned to Class I ,
Classification	Class I , According to Rule I , Annex VIII , Chapter III of EU Medical Device Regulation (EU) 2017/745
Date	06.07.2022

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

DEXXON ENERJİ SANAYİ VE TİCARET A.Ş. declares that the 2017/745 Medical Device Regulation has fulfilled the applicable requirements and responsibility has been taken for the above-described product groups.

*The above mentioned declaration of conformity is exclusively under the responsibility of **DEXXON ENERJİ SANAYİ VE TİCARET A.Ş.** This declaration will cease to be valid if the product specified above is replaced.*

Declarative DEXXON ENERJİ SANAYİ VE TİCARET A.Ş.
Signed by: Murat KOÇ
President
Date : July 06, 2022



