

## EU Declaration of Conformity

<b>Manufacturer</b>	<b>DEXXON ENERJİ SANAYİ VE TİCARET A.Ş.</b>
<b>Adress</b>	Mahmutbey Mah., Soğuksu Cad., No:16 Kat: 9 Trade Tower Bağcılar / İSTANBUL
<b>Medical Device Name</b>	Disposable Non-Sterile Surgical SMMS Gown
<b>Article No</b>	DXNMD-DNSMG SMMS08
<b>Classification</b>	Class I , According to Rule I , Annex VIII , Chapter III of EU Medical Device Regulation (EU) 2017/745
<b>Brand Name</b>	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.*

<b>Product category:</b>	Disposable Non-Sterile Surgical Gown
<b>Conformity Assessment Route</b>	Annex II, Annex III Medical Device Regulation ( EU 2017/ 745 )
<b>Applicable Harmonised Standards</b>	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
<b>Rule</b>	Rule 1, Annex VIII, Regulation (EU) 2017/745
<b>Conformity Assessment Procedure</b>	Annex IX of Regulation (EU) 2017/745
<b>Risk of the Device</b>	The Medical Device has been assigned to Class I ,
<b>Classification</b>	Class I , According to Rule I , Annex VIII , Chapter III of EU Medical Device Regulation (EU) 2017/745
<b>Date</b>	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

