Declaration of Conformity

DEXXON MEDICAL

CE

EU Declaration of Conformity

We,

DEXXON ENERJİ SAN VE TİC. A.Ş.

İstanbul Vizyon Park Ofis Plaza 29 Ekim Cd., 34197 Bahçelievler/İstanbul-TURKEY
declare under our sole responsibility that the medical product listed below

Product Description	DISPOSABLE NON-STERILE MEDICAL FACE MASK
Article No	DRYMY DNDSFM01
Type	Type II R
Manufacturer	DEXXON ENERJİ SAN VE TİC. A.Ş.
Brand Name	DEXXON MEDICAL

*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.*

That the medical device listed above meets the provision of the Regulation (EU) MDR 2017/745 for medical devices.

*The medical devices has 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 : **EN 14683:2019 +AC:2019 (Type II R)** bacterial filtration efficiency, splash resistance, biocompatibility, and microbiological purity.*

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 below complies with the general safety and performance requirements of Regulation (EU) 2017/745 by meeting the followning standarts:

Conformity Assessment Route	Medical Device Regulation 2017/ 745 Annex VIII
Applicable Harmonised Standards	EN 14683: 2019 +AC: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 II and 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 Type II R

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

DEXXON ENERJİ SAN VE TİC. 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 SAN VE TİC. A.Ş.***
This declaration will cease to be valid if the product specified above is replaced.

07.01.2021
Murat Koç
Genaral Manager

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