DRYMY

NVA
QUALITY CERTIFICATION

CE

CE DECLARATION OF CONFORMITY

Manufacturer	: **DRYMAY MİM. MÜH. SAN VE TİC. LTD. ŞTİ**
Address	: Sultan Orhan Mahallesi 1181/3 Sok No:10 Gebze / Kocaeli / TURKEY

The manufacturer declares under his sole responsibility that:
The medical product listed below

Product Description	DISPOSABLE NON-STERILE SURGICAL GOWN
Article No	DRYMY DNSMG01
Other features	SS Standard Medical Gown , Non Reusable, Non-sterile
Colour	Medical Blue
Manufacturer	DRYMAY MİM. MÜH. SAN VE TİC. LTD. ŞTİ
Brand Name	DRYMY

*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 have 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 13795-1:2019**, physical properties tests, 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 above 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 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 II and III of Regulation (EU) 2017/745
Risk of the Device	The Medical Device has been assigned to Class I
Classification	Class I
Certificate No	NVA-EC-22011201
Release Date	12.01.2022
Validity Date	12.01.2023

Digitally signed by Cobzari-Turcan Rodica
Date: 2022.05.04 17:51:48 EEST
Reason: MoldSign Signature
Location: Moldova

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.*

***DRYMAY MİM. MÜH. SAN VE TİC. LTD. ŞTİ.** 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.

DRYMAY MİM. MÜH. SAN. VE TİC. LTD. ŞTİ.

DECLARATIVE
MURAT TECER
GENERAL MANAGER

APPROVAL
NVA QUALITY CERTIFICATION

NVA
QUALITY CERTIFICATION

Manufacturer : DRYMAY MİM. MÜH. SAN VE TİC. LTD. ŞTİ.
NVA KALİTE TEST ÖLÇÜM HİZMETLERİ EĞİTİM VE BELGELENDİRME TİC. LTD. ŞTİ.
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