

DECLARATION OF CONFORMITY

Section No	TD-07/5.1-En
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Company Name : Su Biyomedikal Sistemler ve Sağlık Hizmetleri San. ve Tic. A.Ş.
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PRODUCT NAME	REFERENCE No.	PRODUCT DESCRIPTION	UDI-DI	CLASS and Rule	GMDN Code
SUBMED SURGICAL GOWN	NG-001-1	STANDARD SURGICAL GOWN,S	8681305210558	Class I Rule 1	35091
	NG-001-2	STANDARD SURGICAL GOWN, M	8681305211357		
	NG-001-3	STANDARD SURGICAL GOWN, L	8681305211340		
	NG-001-4	STANDARD SURGICAL GOWN, XL	8681305211364		
	NG-001-5	STANDARD SURGICAL GOWN, XXL	8681305211371		
	NG-001-6	STANDARD SURGICAL GOWN, XXXL	8681305211043		
	NG-002-1	REINFORCED SURGICAL GOWN, S	8681305211395		
	NG-002-2	REINFORCED SURGICAL GOWN , M	8681305211401		
	NG-002-3	REINFORCED SURGICAL GOWN, L	8681305211418		
	NG-002-4	REINFORCED SURGICAL GOWN , XL	8681305211425		
	NG-002-5	REINFORCED SURGICAL GOWN, XXL	8681305211432		
	NG-002-6	REINFORCED SURGICAL GOWN , XXXL	8681305210435		
	NG-003-1	FULL REINFORCED SURGICAL GOWN, S	8681305211449		
	NG-003-2	FULL REINFORCED SURGICAL GOWN, M	8681305211456		
	NG-003-3	FULL REINFORCED SURGICAL GOWN, L	8681305211463		
	NG-003-4	FULL REINFORCED SURGICAL GOWN, XL	8681305211470		
	NG-003-5	FULL REINFORCED SURGICAL GOWN, XXL	8681305211487		
	NG-003-6	FULL REINFORCED SURGICAL GOWN ,XXXL	8681305210534		
	NG-004	EXTRA REINFORCED SURGICAL GOWN	8681305210428		
	NG-005-1	PATIENT GOWN , WITHOUT CUFF , 30 gr/m2	8681305210398		
	NG-005-2	PATIENT GOWN , WITHOUT CUFF , 35 gr/m2	8681305210503		
	NG-005-3	PATIENT GOWN , WITHOUT CUFF , 40 gr/m2	8681305210411		
	NG-006-1	STANDARD SURGICAL L GOWN	8681305210497		
	NG-006-2	PATIENT GOWN , WITH CUFF , 35 gr/m2	8681305210404		
	NG-006-3	PATIENT GOWN , WITH CUFF , 40 gr/m2	8681305210510		
	NG-007	EXAMINATION GOWN	8681305210527		
	NG-008	ISOLATION GOWN	8681305219346		

Intended Use : They are medical devices used for the prevention of diseases.

Conformity Assessment Procedure: Su Biyomedikal uses the following procedures for the CE-labeling of their products according the Regulation MDR 2017/745:

Class I : EC conformity declaration according to Article 19 + Annex II, III

Related Standards: UNI CEI EN ISO 13485:2016, EN ISO 9001:2015, EN ISO 14971:2019

This declaration of conformity is issued under the sole responsibility of Su Biyomedikal. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the Quality System approval to EN ISO 13485:2016 issued by Kiwa Belgelendirme A. Ş. Certificate No : M 9902

All supporting documentation is retained at the premises of the manufacturer.

City, Date : İstanbul, 11.06.2021

Signature,Stamp

Name : Yusuf Yiğit Akkuş

Position : General Manager

SU BİYOMEDİKAL SİSTEMLER VE
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CE