

DECLARATION OF CONFORMITY

Bölüm No	TD-07/5.2-1-Tr
Rev. Tarihi	22.02.2021
Rev. No	05
Sayfa No	1 / 1

Company Name : Su Biyomedikal Sistemler ve Sağlık Hizmetleri San. ve Tic. Ltd. Şti.
Address : Orhangazi mah. 1673. Sok. No:20/ 2-3 Esenyurt İstanbul Turkey
Tel : +90 212 320 37 53
Fax : +90 212 320 53 51
Web : www.submed.com.tr
E-mail : info@submed.com.tr

Product Group	Product Name	Reference No	GMDN Codes	Classification
SUBMED SURGICAL GOWNS	SURGICAL SCRUB SUIT, M	NSS-001-2	35091	Class I Rule 1
	SURGICAL SCRUB SUIT, L	NSS-001-3	35091	Class I Rule 1
	SURGICAL SCRUB SUIT, XL	NSS-001-4	35091	Class I Rule 1
	SURGICAL SCRUB SUIT, XXL	NSS-001-5	35091	Class I Rule 1

Classification: Class I (Non-sterile)

Conformity Assessment Procedure: Annex VII

Related Standards : EN ISO 13485, EN ISO 14971, EN 13795, EN ISO 10993

We herewith declare on our own responsibility to meet the provisions of the Council Directive 93/42/EEC with amended directive 2007/47/EC for Medical Device Directive.

Signature, Stamp

City, Date : Istanbul, 22.02.2021 :
Name : Yusuf Yiğit Akkuş
Position : General Manager

SU BİYOMEDİKAL SİSTEMLER VE
SAĞLIK HİZMETLERİ SAN. VE TİCARET LTD.ŞTİ.
Orhangazi Mahallesi / 1673. Sokak No:20/2-3
Esenyurt / İST. Tis No: 743756 Tel: 0212 320 37 53
Fax: 0212 320 53 51 Yenikapı V.D.: 781 046 0454
Mersis No: 0701 0460 4540 0010