

# DECLARATION OF CONFORMITY

Section No	TD-05/5.1-En
Rev. Date	14.06.2021
Rev. No	10
Page No	1 / 1

**Company Name** : Su Biyomedikal Sistemler ve Sağlık Hizmetleri San. ve Tic. A. Ş.  
**Address** : Orhangazi mah. 1673. Sok. Kat: 2-3 Esenyurt İstanbul Türkiye  
**Tel** : +90 212 320 37 53  
**Fax** : +90 212 320 53 51  
**Web** : www.submed.com.tr  
**E-mail** : [info@submed.com.tr](mailto:info@submed.com.tr)

PRODUCT GROUP NAME	REFERENCE No.	PRODUCT NAME	CLASS and Rule	GMDN Code
SUBMED SURGICAL SETS	SPC-089	Ophtalmology pack	Class IIa Rule 6	35091
	SBF-801	Abdominal surgery set	Class Is Rule 4	35091
	SBF-922-2	Angiography surgical set	Class Is Rule 4	35091
	SBF-810	Arthroscopy set	Class Is Rule 4	35091
	SST-15-A	By-pass Surgery Set	Class Is Rule 4	35091
	SST-021	Cesarean surgery Set	Class Is Rule 4	35091
	SST-026	Eye surgery Set	Class Is Rule 4	35091
	SST-012-A	Hip Arthroplasty set	Class Is Rule 4	35091
	SBF-803-1	Laparoscopy Surgery Set	Class Is Rule 4	35091
	SST-005	Laparotomy Surgery Set	Class Is Rule 4	35091
	SBF-815-1	Shoulder Surgery Set	Class Is Rule 4	35091
	SST-001-A	Universal Surgery Set	Class Is Rule 4	35091
	SST-013-A	Vertebra Surgery Set	Class Is Rule 4	35091
	SBF-801	Abdominal surgery set	Class Is Rule 4	35091
	SBF-922-2	Angiography surgical set	Class Is Rule 4	35091

**Conformity Assessment Procedure:** Annex V

**Related Standards:** ISO 13485, ISO 9001, ISO 11135, ISO 14971

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.

**Notified Body** : KIWA Belgelendirme Hizmetleri A.Ş.  
**NB Address** : İTOSB 9. Cad. No: 15 Tepeören, Tuzla - İstanbul TÜRKİYE  
**NB Identification Number** : 1984  
**EC Certificate Number** : 1984-MDD-14-266  
**Issued Date** : 07 May 2021  
**Revision No** : 7  
**Expiry Date** : 27 May 2024

**City, Date** : İstanbul, 14.06.2021  
**Name** : Yusuf Yiğit Akkuş  
**Position** : General Manager

Signature, Stamp

SU BİYOMEDİKAL SİSTEMLER VE SAĞLIK HİZMETLERİ SAN. VE TİCARET LTD.ŞTİ.  
Orhangazi Mahallesi 1673. Sokak No:20/2-3  
Esenyurt / İST. Ts.No: 749756 / Tel: 0212 320 37 53  
Fax: 0212 320 53 51 Beğenli Kurumlar V.D.: 784 046 0454  
Mersis No: 0781 0400 4540 0010