

# DECLARATION OF CONFORMITY

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**Company Name** : Su Biyomedikal Sistemler ve Sağlık Hizmetleri San. ve Tic. A.Ş.  
**Address** : Orhan Gazi mah. 1673. Sok No:20 Esenyurt İstanbul  
**Tel** : +90 212 320 37 53  
**Fax** : +90 212 320 53 51  
**Web** : www.submed .com.tr  
**E-mail** : info@submed.com.tr

Product Name	Reference No	GMDN Code	Class and Rule
Major Angiography Procedure Pack	ASP-001-5	33961	Class IIa Rule 6
Angiography Surgery Pack	ASP-001-6	33961	Class IIa Rule 6

**Conformity Assessment Procedure** : Annex V  
**Related Standards** : EN ISO 13485, EN ISO 9001, EN ISO 11135, EN ISO 14971

We herewith declare on our own responsibility that the above mentioned 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 TURKEY  
**NB Identification Number** : 1984  
**EC Certificate Number** : 1984-MDD-14-266  
**Expiry Date** : 27 May 2024

Signature, Stamp

**City Date** : İstanbul, 07.01.2022  
**Name** : Yusuf Yiğit Akkuş  
**Position** : General Manager

**SU BİYOMEDİKAL SİSTEMLER VE SAĞLIK HİZMETLERİ SANAYİ VE TİCARET A.Ş.**  
Orhangazi Mah. 1673 Sk. No:20 Esenyurt / İSTANBUL  
Tel: 0212 320 37 53 Faks: 0212 320 53 51  
Yenikapı V.D.: 7810897506 Tic.Sic. No: 749756-0