

DECLARATION OF CONFORMITY

Section No	TD-06/5.2-1-En
Rev Date	17.02.2022
Rev. No	01
Page No	1/1

Company Name : Su Biyomedikal Sistemler ve Sağlık Hizmetleri San. ve Tic. A.Ş.
Address : Orhangazi 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
ANGIOGRAPHY SURGERY PACK	ASP-001-7	33961	Class 2a Rule 6

Conformity Assessment Procedure : Annex V
Related Standards : EN ISO 13485, EN ISO 9001, EN ISO 11135, EN ISO 14971, EN 13795-1

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 TÜRKİYE
NB Identification Number : 1984
EC Certificate Number : 1984-MDD-14-266
Expiry Date : 27 May 2024

Signature, Stamp

City Date : İstanbul, 17.02.2022
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