

DECLARATION OF CONFORMITY

Section No	TD-05/5.1-En
Rev Date	31.05.2021
Rev. No	07
Page 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 Name	Reference No	GMDN Code	Class and Rule
Angiography Prosedure Set	SPC-003-2	33961	Class Is Rule 4

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

Signature, Stamp

SU BİYOMEDİKAL SİSTEMLER VE
SAĞLIK HİZMETLERİ SAN. VE TİCARET LTD.ŞTİ.
Orhangazi Mahallesi 1673 Sokak No:20/2-3
Esenyurt / İST. İl No: 249756 Tel: 0212 320 37 53
Fax: 0212 320 53 51 Boğaziçi Kurumlar V.D.: 781 046 0454
Mersis No: 0781046045400010

DECLARATION OF CONFORMITY

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

City Date : İstanbul, 31.05.2021
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. İl No: 249756 Tel: 0212 320 37 53
Fax: 0212 320 53 51 Boğaziçi Kurumlar V.D.: 781 046 0454
Mersis No: 0781 0460 4540 0010