

# DECLARATION OF CONFORMITY

Section No	TD-07/5.2-1-En
Rev Date	02.09.2021
Rev. No	02
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**Company Name** : Su Biyomedikal Sistemler ve Sağlık Hizmetleri San. ve Tic. A.Ş.  
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Product Name	Reference No	GMDN Code	Class and Rule
SUBMED Angiography Pack	ASP-001	33961	Class IIa Rule 6
SUBMED Radial Angiography Pack	ASP-002	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 TÜRKİYE  
**NB Identification Number** : 1984  
**EC Certificate Number** : 1984-MDD-14-266  
**Expiry Date** : 27 May 2024

*Signature, Stamp*

**City Date** : İstanbul, 02.09.2021  
**Name** : Yusuf Yiğit Akkuş  
**Position** : General Manager

**SU BİYOMEDİKAL SİSTEMLER VE  
SAĞLIK HİZMETLERİ SANAYİ VE TİCARET A.Ş.**  
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