

DECLARATION OF CONFORMITY

Section No	TD-05/5.2-1-En
Rev Date	14.12.2021
Rev. No	01
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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
ANGIOGRAPHY SURGERY PACK	ASP-001-1	33961	Class 2a Rule 6
ANGIOGRAPHY SURGERY PACK	ASP-001-2	33961	Class 1s Rule 1

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

City Date : İstanbul, 14.12.2021
Name : Yusuf Yiğit Akkuş
Position : General Manager

Signature, Stamp


SUBMED
BİYOMEDİKAL SİSTEMLER
PAZARLAMA DİŞTİC. A.Ş.
Orhangazi Mahallesi 1673 Sok. No: 20/2-3
Esenyurt/İST. Esenyurt V.D. 7821159861