

DECLARATION OF CONFORMITY

Section No	TD-06/5.1-En
Rev. Date	22.02.2021
Rev. No	11
Page No	1 / 1

Company Name : Su Biyomedikal Sistemler ve Sağlık Hizmetleri San. ve Tic. Ltd. Şti.

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PRODUCT NAME	REFERENCE No.	PRODUCT DESCRIPTION	GMDN No:
SURGICAL SET	SBF-1012	EYE DRAPE	47783

Classification: Class 1S Rule 1

Conformity Assessment Procedure: Annex V

Related Standards: ISO 13485, ISO 9001, ISO 11135, ISO 14971

We herewith declare on our own responsibility that mentioned product 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 : İstanbul Tuzla Organize Sanayi Bölgesi (İTOSB) Eski Ankara Asfaltı Orhanlı, 34957
Tepeören - İstanbul TÜRKİYE

NB Identification Number : 1984

EC Certificate Number : 1984-MDD-14-266

Revision No : 6

Issued Date : 17 January 2020

Expiry Date : 27 May 2024

City, Date : İstanbul, 22.02.2021

Signature, Stamp

Name : Yusuf Yiğit Akkuş

Position : General Manager

SU BİYOMEDİKAL SİSTEMLER VE
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