

DECLARATION OF CONFORMITY

Section No	TD-08/5.1-En
Rev. Date	12.05.2022
Rev. No	02
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 Turkey
Tel : +90 212 320 37 53
Fax : +90 212 320 53 51
E-mail : info@submed.com.tr
Web : www.submed.com.tr
SRN (Single Registration Number) : TR-MF-000017528

Product Group	Reference No	Product Name	Basic UDI-DI	GMDN Codes	Classification
Surgical Masks	LB002	Legal Beauty Surgical Mask, Blue Color	868130521TD-088P	35177	Class I Rule 1

Intended Use : They are medical devices used for the prevention of diseases.

Conformity Assessment Procedure: Su Biyomedikal uses the following procedures for the CE-labeling of their products according the Regulation MDR 2017/745:

Class I: EC conformity declaration according to Article 19 + Annex II, III

Related Standards: EN ISO 13485:2016, EN ISO 14971:2019, EN 14683:2019

This declaration of conformity is issued under the sole responsibility of Su Biyomedikal. We hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. This declaration is supported by the Quality System approval to EN ISO 13485:2016 issued by Kiwa Belgelendirme A. Ş. Certificate No : M 9902
All supporting documentation is retained at the premises of the manufacturer.

City, Date : İstanbul, 12.05.2022
Name : Yusuf Yiğit Akkuş
Position : General Manager

SU BIYOMEDİKAL 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