

DECLARATION OF CONFORMITY

Section No	TD-07/5.1-En
Rev. Date	11.06.2021
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Company Name : Su Biyomedikal Sistemler ve Sağlık Hizmetleri San. ve Tic. A.Ş.
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Product Group	Reference No	Product Name	UDI-DI	GMDN Codes	Classification
SUBMED Face Masks	MS-001-1	Surgical Mask	8682780970111	35177	Class 1 Rule 1
	MS-001-2	Surgical Mask	8682780970128		
	MS-001-3	Surgical Mask	8682780970135		
	MS-001-4	Surgical Mask	8681305219339		
	MS-001-5	Surgical Mask	8682780970142		
	MS-001-6	Surgical Mask	8682780970159		
	MS-001-1	Surgical Mask	8682780970111		
	MS-001-2	Surgical Mask	8682780970128		
MS-001-3	Surgical Mask	8682780970135			

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: UNI CEI EN ISO 13485:2016, EN ISO 9001:2015, EN ISO 14971:2019

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, 11.06.2021
Name : Yusuf Yiğit Akkuş
Position : General Manager

Signature,Stamp

SU BİYOMEDİKAL SİSTEMLER VE
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