

# DECLARATION OF CONFORMITY

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|------------|--------------|
| Section No | TD-07/5.1-En |
| Rev. Date  | 17.09.2021   |
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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  | Basic UDI-DI       | GMDN Codes | Classification |
|---------------|--------------|---------------|--------------------|------------|----------------|
| SUBMED Mask   | MS001-4      | Surgical Mask | 868130521MS001-46E | 47783      | 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**: UNI CEI EN ISO 13485:2016, EN ISO 9001:2015, EN ISO 14971:2019, EN 13795-1:2019

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, 17.09.2021  
**Name** : Yusuf Yiğit Akkuş  
**Position** : General Manager

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