

DECLARATION OF CONFORMITY

Section No	TD-07/5.1-En
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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	MS001-6	Surgical Kids Mask	868130521MS001-66J	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, 02.11.2021
Name : Yusuf Yiğit Akkuş
Position : General Manager

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