SZUTEST

EC CERTIFICATE

According to Annex V of the Directive 93/42/EEC on Medical Devices

Production Quality Assurance System

Certificate Number: 2195-MED-1935001

Manufacturer: **Kims Med Co., Ltd.**
#112, #214 Bio Material and Component Service Center, Gwangju Techno Park, 249, Chuam-ro, Buk-gu, Gwangju, Republic of KOREA

Product(s): **Sterile Single Use Instrument for the Delivery of Silicone Gel Implant**

Model(s): REF_01KR

Reference Report No: MM0743-P001-R01, MM0743-P001-R02

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex V, Section 3 of the directive 93/42/EEC on medical devices. This quality assurance system covers those aspects of manufacturing concerned with securing and maintaining safe conditions of the respective product(s) and conforms to the provisions of this Directive. The approved quality system is subject to surveillance pursuant to Annex V, Section 4 of Directive 93/42/EEC and unannounced audits.

Szutest must be informed of any significant changes in the design and/or construction of the product(s). For class I devices with sterile conditions the quality management system evaluation is restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions. For class I devices with measuring function the quality management system evaluation is restricted to the aspects of manufacture concerned with the conformity of the devices with metrological requirements

This EC certificate is valid till 2024-05-26.

Issue Date: 2019-12-16

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş. NOTIFIED BODY 2195

Rukiye BALKAN
Deputy General Manager

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.
Tatlısu Mahallesi, Akif İnan Sk. No:1 Ümraniye 34774 İSTANBUL / TÜRKİYE
Szutest.com.tr

SZUTEST

CERTIFICATE INFO AMENDMENT

SERTİFİKA BİLGİ DEĞİŞİKLİĞİ

According to Article 120(3) of the Regulation (EU) 2017/745 on Medical Devices

(AB) 2017/745 Tıbbi Cihazlar Yönetmeliği Madde 120(3)'ye göre

Effected Certificate Number(s): *Etkilenen Sertifika Numarası(ları):*	**2195-MED-1935001**
Manufacturer: *Üretici*	**Kims Med Co., Ltd.** #214, #317 Bio Material and Component Service Center, Gwangju Techno Park, 249, Chuam-ro, Buk-gu, Gwangju, Republic of KOREA
Product(s): *Ürün(ler)*	*No change*
Model(s): *Model(ler)*	*No change*
Reference Report No: *Referans Rapor No*	MM0743-P006-R01, MM0743-P006-R02
Definition of the Change: *Değişikliğin Tanımı*	Address change

SZUTEST, Notified Body 2195, declares and the above mentioned manufacturer has initiated an insignificant change according to Article 120(3) of (EU) 2017/745 and MDCG 2020-3 guidance and therefore the information on the effected 93/42/EEC certificate(s) has been changed as described above.

This document is a confirmation for authorities and cannot be used as other purposes.

2195 kimlik numaralı Onaylanmış Kuruluş SZUTEST, yukarıda belirtilen üreticinin (AB) 2017/745 Regülasyonu Madde 120(3)'e ve MDCG 2020-3 rehber dokümanına göre önemli olmayan bir değişiklik yürüttüğünü ve bu sebeple etkilenen 93/42/AT sertifika(lar)ındaki bilgilerin yukarıdaki gibi değiştiğini beyan eder.

Bu doküman yetkili otoriteler için bir onay niteliğinde olup farklı bir amaçla kullanılamaz.

Issue Date/*Yayın Tarihi:* 2022-08-02

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.

Rukiye BALKAN
Deputy General Manager
Genel Müdür Yardımcısı

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.
Tatlısu Mahallesi, Akif İnan Sk. No:1 Ümraniye 34774 İSTANBUL / TÜRKİYE
Szutest.com.tr