SZUTEST

EC CERTIFICATE

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

Full Quality Assurance System

Certificate Number: 2195-MED-2017701

Manufacturer: **Sometech Inc.**
1201, 1204, Ace High-end Tower II, 61 Digital-ro 26-gil, Guro-gu, Seoul, Republic of KOREA

Product(s): **1. High Frequency Electrosurgical Unit including Electrodes**
2. Non-sterile Rigid Laparoscope

Model(s): 1. ST-501, A04, BS2510, BS3512, BL4015, BL4515, BL5025, BT7060, C01, C02, C03, C04, C05, C06, C07, C08, C09, C10, C11, D01, D02, D03, D04, D05, D06, D07, D08, D18, E01, E02, E03, E03a, E03b, E04, E04a, E04b, E05, E05a, E06, E07, E08, E09, E09a, E10a, E10b, E10c, E11a, E11b, E11c, F01, F02, F03, F04, F05, G01, G02, G03, J01, J02, J03, J04, J05, J06, J07, J08, J09, J10, J11, J12, J13, K01, K02, K03, K04, K05, K11, K12, L01, L02, L03, L04, L05, L11, L12, M01, M02, M03, M04, M05, M11, M12, N01, N02, N03, N04, N05, N11, N12, O01, O02, O03, O04, O05, O11, O12, T16, T17
2. TrueEYE Tri-00 (10⌀), TrueEYE Tri-30 (10⌀)

Reference Report No: MM0758-P001-R01, MM0758-P001-R02, MM0758-P002-R01, MM0758-P002-R03

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II (excluding section 4), 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 II, Section 5 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: 2020-06-25
Revision No.: 01 Rev.
Revision Date: 2021-04-16

Rukiye BALKAN
Deputy General Manager

This version of certificate has come into force on 23.03.2017. MT 2195-MED-2017701 Rev.01

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