SZUTEST

EC CERTIFICATE

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

Full Quality Assurance System

Certificate Number: 2195-MED-381510001

Manufacturer:	**MCTBIO** 46, Chobu-ro, Mohyeon-myeon, Cheoin-gu, Yongin-si, Gyeonggi-do, Republic of KOREA
Product(s):	**Non-Sterile Single Use Maxillofacial Fixation Screw**
Model(s):	MC-Bone Tac, MC-MI-Screw, MC-Orthodontic Screw
Reference Report No:	MM0334-P005-R01, MM0334-P005-R02

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.

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş. NOTIFIED BODY 2195

Rukiye BALKAN
Deputy General Manager

Issue Date:	2015-04-10
Revision No.:	03 Recertification
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