SZUTEST
NOTIFIED BODY 2195

EC CERTIFICATE

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

Production Quality Assurance System

Certificate Number: 2195-MED-1221901

Manufacturer: **BioMTA**
(Yongsan-dong), 41 Techno8-ro, Yuseong-gu, Daejeon, Korea

Product(s): **Root Canal Filling Material**

Model(s): **OrthoMTA (Mineral Trioxide Aggregate)**
RetroMTA (OrthoMTA II)

Reference Report No: 2195-MED-1112004, 2195-MED-1211002, MM0088-P002-R01, MM0088-P002-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).

This EC certificate is valid till 2019-12-19.

Issue Date: 2012-08-06
Revision No.: 02 Recertification
Revision Date: 2016-12-20

SZUTEST TEKNİK KONTROL VE BELGELENDİRME HİZM. TİC. LTD. ŞTİ. ONAYLANMIŞ KURULUŞ 2195

Rukiye BALKAN
Deputy General Manager

This version of certificate has come into force on 2013.11.06 1/1 2195-MED- 1221901 Rev.02

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