SZUTEST

EC CERTIFICATE

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

Full Quality Assurance System

Certificate Number: 2195-MED-1306301

Manufacturer: **Meta Biomed Co., Ltd.**
270, Osongsaengmyeong 1-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, Korea

Product(s): **(1) Sterile Absorbable Bone Graft**
(2) Sterile Bone Cement

Model(s): (1) Sorbone
(2) NTCem-Spine

Reference Report No: MM0364-P006-R01, MM0364-P006-R02

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II, Section 3 and Section 4 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).

This EC certificate is valid till 2021-03-02.

Issue Date: 2013-03-04
Revision No.: 04 Recertification
Revision Date: 2018-03-03

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş. NOTIFIED BODY 2195

Rukiye BALKAN
Deputy General Manager

This version of certificate has come into force on 23.03.2017. M1: 2195-MED-1306301 Rev.04

FR.MED.37 R:04