SZUTEST

EC CERTIFICATE

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

Production Quality Assurance System

Certificate Number: 2195-MED-1328403

Manufacturer: **NEXOBIO Co., Ltd.**
601, Center B/D, 27, Sanseong-ro 92beon-gil, Sandang-gu, Cheongju-si, Chungcheongbuk-do, Republic of KOREA

Product(s):
1. Dental Restorative Materials
2. Temporary Crown and In & Onlay Resin
3. Dental Etchant
4. Dental Cement (Non eugenol Temporary Cement)
5. Pit and Fissure Sealant
6. Root Canal Filling Material
7. Dental Adhesive

Model(s):
1. Transcen, Transcen Core, Transcen LV, T Com, T Core, T Com Flow
2. Transcen Temp C&B LC, Transcen Temp In&Onlay LC
3. Transcen Etchant
4. TempCem NE, TempCem Implant
5. Transeal F
6. MTA Cem 1.0, MTA Cem 0.14, MTA Cem 0.3
7. T Bond

Reference Report No: MM0393-P008-R01, MM0393-P008-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.

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş. NOTIFIED BODY 2195

Issue Date: 2013-10-11
Revision No.: 05 Recertification
Revision Date: 2020-07-22

Rukiye BALKAN
Deputy General Manager

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