

## EC CERTIFICATE

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

### Full Quality Assurance System

Certificate Number: 2195-MED-1306401

**Manufacturer:**

**OSSTEM ORTHODONTICS Inc.**

Head Office (Ojeon-dong, Byeoksantechnopia), A-1203, 1204, 13,  
& Factory 1: Ojeongonggeop-gil, Uiwang-si, Gyeonggi-do, Republic of KOREA  
Factory 2: 14, Sanbon-ro 55beon-gil, Gunpo-si, Gyeonggi-do, Republic of  
KOREA

**Product(s):**

- (1) Non-Sterile Orthodontic Tube
- (2) Non-Sterile Orthodontic Bracket
- (3) Non-Sterile Orthodontic Wire

**Model(s):**

Product specifications are stated on the following page(s).

**Reference Report No:** MM0242-P006-R01, MM0242-P006-R02, MM0242-P007-R01, MM0242-P008-R01,  
MM0242-P008-R02, MM0242-P009-R01

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: 2013-03-05  
Revision No.: 10 Rev.  
Revision Date: 2021-05-25



Rukiye BALKAN  
Deputy General Manager

# SZUTEST

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## Product Specifications:

(1) Orthodontic Tube		SM TUBE	<b>Single Type</b> ROTH – Bondable, ROTH – Weldable, MBT – Bondable, MBT – Weldable, STANDARD – Bondable <b>Twin Type</b> ROTH – Bondable, ROTH – Weldable, MBT – Bondable, MBT – Weldable
(2) Orthodontic Bracket	Orthodontic Ceramic Bracket	PERFECT CLEAR	ROTH, MBT, Standard
		PERFECT CLEAR II	ROTH, MBT, Standard
		ZEPHYR	ROTH, MBT, Standard
		PERFECT CLEAR II (TRI-EDGE)	ROTH, MBT
		OK REAL RESIN BRACKET	ROTH, MBT, Standard
	Orthodontic Self Ligation Ceramic Bracket	WOW advanced	ROTH, MBT
		MAJESTY-SLC	ROTH, MBT
		MISTRAL CLEAR	ROTH, MBT
		Trinity	MBT
	Orthodontic Metal Bracket	CHOIS LINGUAL BRACKET	DBS, WELD
		MTA	Round tube Semi- round tube Needle tube One side flattened tube Silver tube 2 mm Silver tube 3 mm
		YES Bracket, YES2, MISTRAL	ROTH, MBT
		MAJESTY-SLM	ROTH, MBT
		MISTRAL K	ROTH, MBT
(3) Orthodontic Wire	PERFECT		Ni-Ti
	MTA Wire		012 NiTi 014 NiTi 35°C Thermo-active 012 NiTi 35°C Thermo-active 014 NiTi 40°C Thermo-active 012 NiTi 40°C Thermo-active 014 NiTi 45°C Thermo-active 012 NiTi 45°C Thermo-active 014 NiTi

SZUTEST UYGUNLUK DEĞERLENDİRME A.Ş.

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