



ONAYLANMIŞ KURULUŞ 2195

SZUTEST



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:

HUBIT Co., Ltd.

#1203, #1204, Je-A-Dong, 13 Ojeongongeop-gil, Uiwang-si, Gyeonggi-do, Korea

Product Category(ies):

- (1) Orthodontic Tube
- (2) Orthodontic Bracket
- (3) Orthodontic Appliance
- (4) Orthodontic Mini Screw
- (5) Orthodontic Wire

Brand Name:

- (1) SM TUBE
- (2) PERFECT CLEAR, PERFECT CLEAR II, PERFECT CLEAR II (TRI-EDGE), WOW BRACKET, WOW advanced, OK REAL RESIN BRACKET, YES Bracket, CHOIS LINGUAL BRACKET, MTA and Silver MTA
- (3) CHOI'S HOOK
- (4) Mini Screw
- (5) PERFECT, Gemma, MTA Wire

Type(s)/Model(s):

Specification of Products is staged on 2nd page

Final Report No:

**2195-MED- 1303002, 2195-MED-1304004, 2195-MED-1305008,
2195-MED-1308002**

Szutest, Notified Body 2195, declares that the aforementioned manufacturer has implemented a quality assurance system according to Annex II, 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 safety conditions of the respective product category(ies) and accessories 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.

Szutest must be informed of any significant changes in the design and/or construction of the product category(ies).

This EC certificate is valid till 2018.03.04

Istanbul, 2013.03.05
Rev.03 / 2013.08.06



Mehmet IŞIKLAR
General Manager



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This version of certificate has come into force on 2012.12.24



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Orthodontic Tube	SM TUBE	Single Type ROTH – Bondable, ROTH – Weldable, MBT – Bondable, MBT – Weldable, STANDARD – Bondable
		Twin Type ROTH – Bondable, ROTH – Weldable, MBT – Bondable, MBT – Weldable
Orthodontic Bracket	PERFECT CLEAR	ROTH MBT Standard
	PERFECT CLEAR II	ROTH MBT Standard
	PERFECT CLEAR II (TRI-EDGE)	ROTH MBT
	WOW BRACKET	ROTH MBT
	WOW advanced	ROTH MBT
	OK REAL RESIN BRACKET	ROTH MBT Standard
	YES Bracket	ROTH MBT
	CHOIS LINGUAL BRACKET	DBS WELD
	MTA	ROUND SEMI- ROUND NEEDLE
	Silver MTA	2 mm 3 mm
Orthodontic Appliance	Choi's Hook	
Orthodontic Mini Screw	Mini Screw	STANDARD CROSS HEAD
Orthodontic Wire	PERFECT	S.S Ni-Ti
	Gemma	S.S Ni-Ti
	MTA Wire	General 35°C 40°C 45°C

