

EC DECLARATION OF CONFORMITY



Osstem Implant Co., Ltd

(Manufacturer: Haeundae Plant: 66-16, Bansong-ro 513beon-gil, Haeundae-gu, Busan, Korea

EU Representative: DEUTSCHE OSSTEM GmbH

Mergenthalerallee 25, 65760 Eschborn, Germany)

declares that the subject products are falling within class IIb and in conformity with the essential requirements and provisions of Council Directive 93/42/EEC as amended by 2007/47/EC.

As required by Annex II (excluding section 4) of the above Directive, this Declaration is supported by EC quality system approval certificate issued by Notified Body number 2460, DNV GL Nemko Presafe AS: Veritasveien 3 1363 Høvik Norway, Head office : Veritasveien 1, 1322 HØ VIK, Norway.

• Subject products (Type / Model)

TS SA Fixture System
US SA Fixture System
SS SA Fixture System
TS HA Fixture System
SS HA Fixture System
TS BA Fixture System
TS CA Fixture System
TS SOI Fixture System
SS CA Fixture System
US CA Fixture System
OrthAnchor
MS SA Implant
OssBuilder
Healing Abutment
Bone Screw
Tenting Screw
OB Anchor
Cover Cap
Healing Cap
Cover Screw
Mount

Osstem Implant Co., Ltd is exclusively responsible for the declaration of conformity.

Date & Signature of authorized person

2018.04.12

Keun Sik Chang

Print name

Direct of R&D

Print title

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Chang

Attachment. Detail Product Name of each Type / Model

Type/Model	Product Name	Remark
TS SA Fixture System	1) TSII SA Fixture	
	2) TSII SA Fixture Pre-Mounted	
	3) TSIII SA Fixture	
	4) TSIII SA Fixture Pre-Mounted	
	5) TSIII SA Ultra-Wide Fixture	
	6) TSIII SA Ultra-Wide Fixture Pre-Mounted	
	7) TSIV SA Fixture	
	8) TSIV SA Fixture Pre-Mounted	
	9) TSIV SA Ultra-Wide Fixture	
	10) TSIV SA Ultra-Wide Fixture Pre-Mounted	
US SA Fixture System	11) USII SA Fixture	
	12) USII SA Fixture Pre-Mounted	
	13) USIII SA Fixture	
	14) USIII SA Fixture Pre-Mounted	
	15) USIII SA Ultra-Wide Fixture	
	16) USIII SA Ultra-Wide Fixture Pre-Mounted	
	17) USIV SA Fixture	
	18) USIV SA Fixture Pre-Mounted	
SS SA Fixture System	19) SSII SA Fixture	
	20) SSII SA Fixture Pre-Mounted	
	21) SSIII SA Fixture	
	22) SSIII SA Fixture Pre-Mounted	
	23) SSIII SA Ultra-Wide Fixture	
	24) SSIII SA Ultra-Wide Fixture Pre-Mounted	
TS HA Fixture System	25) TSIII HA Fixture	
	26) TSIII HA Fixture Pre-Mounted	
SS HA Fixture System	27) SSIII HA Fixture	
	28) SSIII HA Fixture Pre-Mounted	
TS BA Fixture System	29) TSIII BA Fixture	
	30) TSIII BA Fixture Pre-Mounted	
	31) TSIII BA Ultra-wide Fixture	
	32) TSIII BA Ultra-wide Fixture Pre-Mounted	
TS CA Fixture System	33) TSII CA Fixture	
	34) TSII CA Fixture Pre-Mounted	
	35) TSIII CA Fixture	
	36) TSIII CA Fixture Pre-Mounted	
	37) TSIII CA Ultra-Wide Fixture	
	38) TSIII CA Ultra-Wide Fixture Pre-Mounted	
	39) TSIV CA Fixture	
	40) TSIV CA Fixture Pre-Mounted	
	41) TSIV CA Ultra-Wide Fixture	
	42) TSIV CA Ultra-Wide Fixture Pre-Mounted	

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TS SOI Fixture System	43) TSIII SOI Fixture	
	44) TSIII SOI Fixture Pre-Mounted	
	45) TSIII SOI Ultra-Wide Fixture	
	46) TSIII SOI Ultra-Wide Fixture Pre-Mounted	
SS CA Fixture System	47) SSII CA Fixture	
	48) SSII CA Fixture Pre-Mounted	
	49) SSII CA Ultra-Wide Fixture	
	50) SSII CA Ultra-Wide Fixture Pre-Mounted	
	51) SSIII CA Fixture	
	52) SSIII CA Fixture Pre-Mounted	
	53) SSIII CA Ultra-Wide Fixture	
	54) SSIII CA Ultra-Wide Fixture Pre-Mounted	
US CA Fixture System	55) USII CA Fixture	
	56) USII CA Fixture Pre-Mounted	
	57) USII CA Ultra-Wide Fixture	
	58) USII CA Ultra-Wide Fixture Pre-Mounted	
	59) USIII CA Fixture	
	60) USIII CA Fixture Pre-Mounted	
	61) USIV CA Fixture	
	62) USIV CA Fixture Pre-Mounted	
OrthAnchor	63) OrthAnchor	
MS SA Implant	64) MS SA Implant	
OssBuilder	65) OssBuilder	
Healing Abutment	66) Healing Abutment	
Bone Screw	67) Bone Screw	
Tenting Screw	68) Tenting Screw	
OB Anchor	69) OB Anchor	
Cover Cap	70) Cover Cap	
Healing Cap	71) Healing Cap	
Cover Screw	72) Cover Screw	
Mount	73) Mount	