Section 5.	Declaration of Conformity	OSSTEM IMPLANT

Osstem Implant Co., Ltd
(Manufacturer: Haeundae Plant: 66-16, Bansong-ro 513beon-gil, Haeundae-gu, Busan, Korea
EU Representative: DEUTSCHE OSSTEM GmbH
Mergenthalerallee 35-37, 65760 Eschborn, Germany)

declares that the subject products are falling within class IIa 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 Presafe AS: Veritasveien 3 1363 Høvik Norway, Head office : Veritasveien 1, 1322 HØVIK, Norway.

- **Subject products (Type / Model)**

KIT System
-Osstem KIT System
-HiOssen KIT System

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

Date & Signature of authorized person

2019.08.31
Keun Sik Chang — Print name
Director of R&D — Print title

Attachment 1. Detail Product Name of each Type / Model

Type/Model	Product Name	Remark
Osstem KIT System	1) New Hanaro KIT	
	2) TS KIT	
	3) Ortho KIT	
	4) MS KIT	
	5) Taper KIT	
	6) Taper Mini KIT	
	7) OsstemGuide KIT	
	8) Prosthetic KIT	
	9) Prosthetic Simple KIT	
	10) 123 KIT	
	11) 123 Full KIT	
	12) 123 KIT–IV	
	13) ESR KIT	
	14) ESR Full KIT	
	15) Parallel Guide KIT	
	16) Smart Guide KIT	
	17) 122 Taper KIT	
	18) 122 Taper Full KIT	
	19) OneGuide KIT	
	20) OnsCas KIT	
	21) OneMS KIT	
	22) 485 KIT	
	23) ORP KIT	
	24) ORP Simple KIT	
	25) 123 Straight Full KIT	
	26) GBR KIT	
	27) ASSIST KIT	
	28) TS Abutment Selection KIT	

	29) CUSTOM KIT	
HiOssen KIT System	30) Taper Ultra Kit	
	31) Standard KIT	
	32) CAS-KIT	
	33) CAS-KIT PLUS	
	34) LAS-KIT	
	35) LAS-KIT Plus	
	36) ESSET KIT	
	37) Ultra KIT	
	38) OssBuilder KIT	
	39) 123 KIT	
	40) 123 Full KIT	
	41) Taper KIT	
	42) Prosthetic KIT	

Attachment 2. Harmonized Standards

Standard Number	Standard Name
Directive 93/42/EEC as amended by 2007/47/EC	Medical Devices Directive
MEDDEV 2.4/Rev.9	Classification of medical devices
MEDDEV 2.7/1 Rev.4	Clinical Evaluation : Guide for manufacturers and notified bodies
NB-MED Rec3	Evaluation of clinical data - Chapter 2.7 Clinical investigations, clinical evaluation
MEDDEV 2.12/1 Rev.8	Guidelines on a medical devices vigilance system
MEDDEV 2.12/2 Rev.2	Post market clinical follow-up studies
EN ISO 11737-1:2006 / AC:2009	Sterilization of medical devices – Microbiological methods – Part 1: Determination of a population of microorganisms on products
EN ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1 : General requirements

EN 1041:2008	Information supplied by the manufacturer of medical devices
ISO 7405:2018	Dentistry - Evaluation of biocompatibility of medical devices used in dentistry
EN ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2010	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
EN ISO 13485:2016	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2012	Medical devices - Application of risk management to medical devices
ASTM F136-13	Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)
ASTM F899-12b	Standard Specification for Wrought Stainless Steels for Surgical Instruments
EN ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1 : General requirements
EN 1041:2008	Information supplied by the manufacturer of medical devices