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 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 Product Assurance AS: Veritasveien 3 1363 Høvik Norway, Head office : Veritasveien 1, 1322 HØVIK, Norway.

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

  TS SA Fixture System
  Healing Abutment
  Cover Screw
  TS Abutment System
  HG Abutment System
  Attachment System
  Protect Cap System

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

Date & Signature of authorized person

2022.01.18

Son Hee Kwon — Print name

Head of RA Department — Print title

Attachment 1. Detail Product Name of each Type / Model

Type/Model	Product Name	Remark
TS SA Fixture System	1) TSII SA Fixture	
	2) TSIII SA Fixture	
	3) TSIII SA Ultra-wide Fixture	
	4) TSIV SA Fixture	
	5) TSIV SA Ultra-wide Fixture	
Healing Abutment	6) Healing Abutment	
Cover Screw	7) Cover Screw	
TS Abutment System	8) TS Rigid Abutment	
	9) TS Transfer Abutment	
	10) TS Angled Abutment	
	11) TS FreeForm ST Abutment	
	12) TS FreeForm Abutment	
	13) TS Gold Cast Abutment	
	14) TS Convertible Abutment	
	15) TS Convertible GoldCast Cylinder	
	16) TS Convertible Temporary Cylinder	
	17) TS Convertible Combination Cylinder	
	18) TS Convertible Angled Cylinder	
	19) TS Convertible NP-Cast Cylinder	
	20) TS Multi NP-Cast Cylinder	
	21) TS Multi Combination Cylinder	
	22) TS Multi Ti Base	
	23) TS OneFit Abutment	
	24) TS NP-Cast Abutment	
	25) TS Quick Temporary Abutment	
	26) TS Temporary Abutment	
	27) TS ZioCera Abutment	
	28) TS ZioCera Angled Abutment	
	29) TS Stud Abutment	
	30) TS Multi Angled Abutment	
	31) TS Multi Abutment	
	32) TS Port Abutment	
	33) TS Port Angled Abutment	
	34) TS Port Angled Head	
	35) TS Link Abutment for Lab	

	36) TS Link Abutment for CEREC	
	37) Pre-milled Abutment	
Attachment System	38) O-ring	
	39) O-ring Retainer	
	40) Port Male	
Protect Cap System	41) TS Rigid Protect Cap	
	42) TS Rigid Retraction Cap	
	43) TS Convertible Protect Cap	
HG Abutment System	44) HG Abutment	

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 556-1:2001	Sterilization of medical devices - Requirements for medical devices to be designated "STERILE" - Part 1: Requirements for terminally sterilized medical devices
EN ISO 15223-1:2021	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
EN ISO 11137-1:2015	Sterilization of health care products – Radiation – Part 1 : Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11137-2:2015	Sterilization of health care products - Radiation- Part 2: Establishing the sterilization dose
ISO 11137-3:2017	Sterilization of health care products - Radiation- Part 3: Guidance on dosimetric aspects of development, validation and routine control
EN ISO 10993-1:2009	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
EN ISO 10993-3:2014	Biological evaluation of medical devices – Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity
EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
EN ISO 10993-6:2009	Biological evaluation of medical devices - Part 6: Tests for local effects after implantation
ISO 10993-10:2010	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
EN ISO 10993-11:2009	Biological evaluation of medical devices - Part 11: Tests for systemic toxicity
EN ISO 10993-12:2012	Biological evaluation of medical devices – Part 12: Sample preparation and reference materials

ISO 7405:2018	Dentistry - Evaluation of biocompatibility of medical devices used in dentistry
EN ISO 11607-1:2009	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO11607-2 :2006	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN 1641:2009	Dentistry - Medical devices for dentistry - Materials
EN 1642:2011	Dentistry - Medical devices for dentistry - Dental implants
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 11737-2:2009	Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
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 F1929-15	Standard test method for detecting seal leaks in porous medical packaging by dye penetration
ASTM F1980-16	Standard guide for accelerated aging of sterile barrier systems for medical devices
ASTM D882-18	Standard test method for tensile properties of thin plastic sheeting
ASTM F88-15	Standard test method for seal strength of flexible barrier materials
ASTM F1140-13	Standard test methods for internal pressurization failure resistance of unrestrained packages
ASTM F1608-16	Standard test method for microbial ranking of porous packaging materials(exposure chamber method)
ASTM F2096-11	Standard test method for detecting gross leaks in packaging by internal pressurization(bubble test)
EN62366 : 2008	Medical devices - Application of usability engineering to medical devices
ISO 14801:2016	Dentistry - Implants - Dynamic fatigue test for endosseous dental implants
ASTM F136-13	Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401)
ASTM F67-13	Standard Specification for Unalloyed Titanium, for Surgical Implant Applications(UNS R50250, UNS R50400, UNS R50550, UNS R50700)
ISO 5832-2:2018	Implants for surgery --Metallic materials – Part 2: Unalloyed titanium
ISO 5832-4:2014	Implants for surgery -- Metallic materials - Part 4: Cobalt-chromium-molybdenum casting alloy
ASTM D792-13	Standard Test Methods for Density and Specific Gravity (Relative Density) of Plastics by Displacement
ASTM F1537-11	Standard Specification for Wrought Cobalt-28Chromium-6Molybdenum Alloys for Surgical Implants (UNS R31537, UNS R31538, and UNS R31539)
ASTM F75-18	Standard Specification for Cobalt-28 Chromium-6 Molybdenum Alloy Castings and Casting Alloy for Surgical Implants (UNS R30075)
ASTM F799-19	Standard Specification for Cobalt-28Chromium-6Molybdenum Alloy Forgings for Surgical Implants (UNS R31537, R31538, R31539)
ASTM F1185-03 (2014)	Standard Specification for Composition of Hydroxyapatite for Surgical Implants