According to the Medical Device Regulation (EU) 2017/745

Manufacturer	Osstem Implant Co., Ltd - Address(Haeundae Plant) : 66-16, Bansong-ro 513beon-gil, Haeundae-gu, Busan, Korea 48002
EU Representative	DEUTSCHE OSSTEM GmbH - Address : Mergenthalerallee 35-37, 65760 Eschborn, Germany
Type / Models	Refer to DoC_Atachment
Classification	**Class I** by Rule 1, 5(Annex VIII of MDR)
Basic UDI-DI	00406CLASSIBUSAN5Q
Conformity Assessment Procedure	Annex IV
WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISIONS OF REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL ON MEDICAL DEVICES UNDER THE EXCLUSIVE RESPONSIBILITY OF MANUFACTURER. ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.	

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

Date & Signature of authorized person

2022.01.26

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
Class I Products	1) TS Scan Body(Intraoral)	
	2) Scan Body Holding Driver	
	3) OneGuide Metal Sleeve	
	4) OneGuide Reamer Drill	
	5) OneGuide Metal Sleeve Press-in Jig	
	6) OneJet SG	

Attachment 2. Harmonized Standards

Standard Number	Standard Name
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
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 10993-11:2018	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 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)
ISO 20795-1:2013	Dentistry – Base Polymers – Par 1 : Denture Base Polymers
ISO 4049:2019	Dentistry – Polymer-based Restorative Materials

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