Declaration of Conformity

Manufacturer: OsteoSys Co., Ltd.
901~914, 9F, JnK Digitaltower, 111 Digital-ro 26, Guro-gu, Seoul,
REPUBLIC OF KOREA

EC Authorized Representative: Finlink
Myllärintie 10/76 00920 Helsinki Finland

Product Group: X-ray Bone Densitometer, Ultrasound Bone Densitometer
Model Name: ***See Appendix***
Classification : ***See Appendix***
Applicated Rule: According to Annex Ⅸ(Rule 10) of the MDD 93/42/EEC
Conformity Assessment Rout : Annex Ⅱ(excluding section 4) of the MDD 93/42/EEC

WE HEREWITH DECLARE THAT THE ABOVE MENTIONED PRODUCTS MEET THE PROVISON OF THE COUNCIL DIRECTIVE 93/42/EEC(AMENDED BY MDD 2007/47/EEC) FOR MEDICAL DEVICES. ALL SUPPORTING DOCUMENTATION IS RETAINED UNDER THE PREMISES OF THE MANUFACTURER.

The manufacturer is exclusively responsible for the declaration of conformity

Standard Applied: ***See Appendix***

Notified Body: DNV GL Presafe AS
Veritasveien 3, 1363 Høvik, Norway
Identification Number: 2460
Certificate Number: EC(286016-2019-CE-KOR-NORWEGIAN)
QS(286015-2019-AQ-KOR-NORWEGIAN)

Place Date of Issue City : Seoul, Korea Date : 2019-04-21
Signature

Room 903, 9F, JnK Digital Tower Building
111 Digital-Ro, Guro-Gu, Seoul, Korea
OsteoSys Co., Ltd.
President Jin-Sik Oh

Name : JinSik Oh Position : President

OsteoSys

Appendix : List of Devices and Standards applied

No.	Product	Model	Class/ Rule	Standards applied
1	**Ultrasound Bone Densitometer**	SONOST-2000	IIa, Rule 10	Harmonized Standards; EN60601-1,EN60601-1-2,EN60601-1-6, EN60601-2-37, EN1041, EN15223-1, EN62304, ISO14971, ISO10993-1, MEDDEV2.7.1
2		SONOST 3000		
3		BeeTLe		
4	**X-Ray Bone Densitometer**	PRIMUS	IIb, Rule 10	Harmonized Standards; EN60601-1, EN60601-1-2, EN60601-1-3, EN60601-1-6, EN60601-2-28, EN1041, EN15223-1,EN62304, ISO14971, ISO10993-1, MEDDEV2.7.1
5		DEXXUM T		
6		EXA-3000		
7		EXCELLUS		