

# 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: CMC Medical Devices & Drugs S.L.

C/Horacio Lengo N<sup>o</sup> 18, CP 29006, Málaga, Spain.

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 PROVISION 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 Product Assurance AS

Veritasveien 3, 1363 Høvik, Norway

Identification Number: 2460

Certificate Number: EC(286016-2019-CE-KOR-NA-PS Rev 5.0)

QS(286015-2019-AQ-KOR-NA-PS Rev 2.0)

Place Date of Issue    City : Seoul, Korea    Date : 2020-11-04

Signature



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Name: Young-Bok Ahn

Position : President

**OsteoSys**

**Appendix : List of Devices and Standards applied**

No.	Product	Model	Class/ Rule	Standards applied
1	<b>Ultrasound Bone Densitometer</b>	SONOST-2000	IIa, Rule 10	Harmonized Standards; EN 60601-1:2006/A1:2013, EN 60601-1-2:2015, EN 60601-1-6:2010/A1:2013, EN60601-2- 37:2008, EN 1041:2008, EN ISO 15223-1:2016, EN 62304:2006/AC:2008, ENISO14971:2012, ENISO10993-1:2009/AC:2010, MEDDEV 2.7.1 rev.4
2		SONOST 3000		
3		BeeTLe		
4	<b>X-Ray Bone Densitometer</b>	PRIMUS	IIb, Rule 10	Harmonized Standards; EN 60601-1:2006/A1:2013, EN 60601-1-2:2015, EN 60601-1-3:2008/A1:2013, EN 60601-1- 6:2010/A1:2013, EN 60601-2-28:2010, EN 1041:2008, EN ISO 15223-1:2016, EN 62304:2006/AC:2008, ENISO14971:2012, ENISO10993-1:2009/AC:2010, MEDDEV 2.7.1 rev.4
5		DEXXUM T		
6		EXA-3000		
7		EXCELLUS		
8		DEXXUM T Quantum		