DOC No.: OT00-CE-DOC
Date / Rev. no.: 2021.11.01 /7.0

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 Nº 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 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***

Digitally signed by Ceaicovschi Tudor
Date: 2026.06.10 16:31:21 EEST
Reason: MoldSign Signature
Location: Moldova
MOLDOVA EUROPEANĂ

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

Name: Young-Bok Ahn 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; 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	**X-Ray Bone Densitometer**	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		