

## SPECIFICAȚIA TEHNICĂ

Model: BeeTLE, producător OsteoSys, Coreea de Sud

| Specificatie tehnica deplina solicitata                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Specificatie tehnica deplina propusă                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <p><b>Dispozitiv medical mobil, wireless, cu ultrasunete utilizat pentru măsurarea densității osoase.</b></p> <ul style="list-style-type: none"> <li>• timpul de scanare 5 sec. +/- 2 sec. pentru măsurarea densității minerale a calcaneului.</li> <li>• echipat cu funcții NFC și GPS.</li> <li>• măsurătorile vor fi realizate rapid, printr-o singură atingere, și sunt gestionate prin aplicația pe PC.</li> <li>• trebuie să fie echipat cu o baterie integrată reîncărcabilă și cu o baterie externă ce poate fi utilizată în caz de urgență.</li> </ul> <p>Caracteristici tehnice:</p> <ul style="list-style-type: none"> <li>• Metoda de măsurare: Ultrasunete (QUS);</li> <li>• Parametri de măsurare: BQI, BUA, SOS, T-Score, Z-Score, raportul T-Score și Z-Score;</li> <li>• Reproducibilitate: <ul style="list-style-type: none"> <li>– BUA &lt; 1.5% CV;</li> <li>– SOS &lt; 0.2 % CV;</li> <li>– BQI &lt; 1.5 CV;</li> </ul> </li> <li>• Frecvență: 50 / 60 Hz;</li> <li>• Putere: 10W;</li> <li>• Baterie: 3.6 V, 6290 mAh;</li> <li>• Dimensiuni: 250 x 337 x 145 mm.</li> </ul> <p>Dispozitivul se completează cu tabletă PC, imprimantă, dispozitiv de calibrare (Phantom), accesorii pentru ajustarea la dimensiunile particulare a piciorului beneficiarului, manualul de utilizare.</p> | <p><b>Dispozitiv medical mobil, wireless, cu ultrasunete utilizat pentru măsurarea densității osoase.</b></p> <ul style="list-style-type: none"> <li>• timpul de scanare 5 sec. +/- 2 sec. pentru măsurarea densității minerale a calcaneului. <b>DA – 5 secunde</b></li> <li>• echipat cu funcții NFC și GPS. <b>DA</b></li> <li>• măsurătorile vor fi realizate rapid, printr-o singură atingere, și sunt gestionate prin aplicația pe PC. <b>DA</b></li> <li>• trebuie să fie echipat cu o baterie integrată reîncărcabilă și cu o baterie externă ce poate fi utilizată în caz de urgență. <b>DA</b></li> </ul> <p>Caracteristici tehnice:</p> <ul style="list-style-type: none"> <li>• Metoda de măsurare: Ultrasunete (QUS); <b>DA</b></li> <li>• Parametri de măsurare: BQI, BUA, SOS, T-Score, Z-Score, raportul T-Score și Z-Score; <b>DA</b></li> <li>• Reproducibilitate: <ul style="list-style-type: none"> <li>– BUA &lt; 1.5% CV; <b>DA</b></li> <li>– SOS &lt; 0.2 % CV; <b>DA</b></li> <li>– BQI &lt; 1.5 CV; <b>DA</b></li> </ul> </li> <li>• Frecvență: 50 / 60 Hz; <b>DA</b></li> <li>• Putere: 10W; <b>DA</b></li> <li>• Baterie: 3.6 V, 6290 mAh; <b>DA</b></li> <li>• Dimensiuni: 250 x 337 x 145 mm. <b>DA</b></li> </ul> <p>Dispozitivul se completează cu tabletă PC, imprimantă, dispozitiv de calibrare (Phantom), accesorii pentru ajustarea la dimensiunile particulare a piciorului beneficiarului, manualul de utilizare. <b>DA</b></p> |

# MANAGEMENT SYSTEM CERTIFICATE

Certificate No.:  
**286015-2019-AQ-KOR-NA-PS Rev 2.0**

Project No.:  
**PRJC-595559-2019-MSL-KOR**

Initial Certification Date:  
**11 April 2019**

Valid Until:  
**17 November 2023**

This is to certify that the management system of:

## **Osteosys Co., Ltd.**

901~914, 9F, JnK Digitaltower, 111 Digital-ro 26, Guro-gu, Seoul, REPUBLIC OF KOREA

Complies with the requirements of:

**ISO 13485:2016/NS-EN ISO 13485:2016**

The Certificate is valid for the following scope:

**Design, Development and Manufacture of X-ray Bone  
Densitometer and Ultrasound Bone Densitometer.  
Manufacture of Ultrasound fracture therapeutic radiator.**

Place and date:  
**Høvik, 4 November 2020**

For:  
**DNV GL PRESAFE AS**



\_\_\_\_\_  
**Eugenie Winger Husebye**

The certificate is digitally verified by blockchain technology. For more info, see  
[www.dnvgl.com/assurance/certificates-in-the-blockchain.html](http://www.dnvgl.com/assurance/certificates-in-the-blockchain.html)



# EC CERTIFICATE

## Full Quality Assurance System

Certificate No.:  
**286016-2019-CE-KOR-NA-PS Rev 5.0**

Project No.:  
**PRJC-595559-2019-MSL-KOR**

Valid Until:  
**17 November 2022**

This is to certify that the quality system of:

### **Osteosys Co., Ltd.**

901~914, 9F, JnK Digitaltower, 111 Digital-ro 26, Guro-gu, Seoul, REPUBLIC OF KOREA

For design, production and final product inspection/testing of:

### **X-ray Bone Densitometer and Ultrasound Bone Densitometer**

Has been assessed with respect to:

### **THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEX II EXCLUDING SECTION 4 OF COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES, AS AMENDED**

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:  
**Høvik, 28 September 2020**

For:  
**DNV GL PRESAFE AS**  
**Notified Body No.: 2460**

**Tone Elise Kolpus**

The certificate is digitally verified by blockchain technology. For more info, see  
[www.dnvgl.com/assurance/certificates-in-the-blockchain.html](http://www.dnvgl.com/assurance/certificates-in-the-blockchain.html)



Certificate No.:  
**286016-2019-CE-KOR-NA-PS Rev 5.0**

Project No.:  
**PRJC-595559-2019-MSL-KOR**

Valid Until:  
**17 November 2022**

## Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

## Certificate history:

| Revision   | Description                                       | Issue Date |
|------------|---------------------------------------------------|------------|
| 0.0        | Original Certificate (Transfer to DNV GL Presafe) | 2019-04-21 |
| 1.0        | Editorial change of product name                  | 2019-04-29 |
| 2.0        | Revised certificate version due to system error   | 2019-05-22 |
| 3.0        | EC Rep. changed.                                  | 2020-07-07 |
| 4.0        | Addition of New model (DEXXUM T Quantum)          | 2020-09-21 |
| <b>5.0</b> | <b>Editorial change of Issue date</b>             | 2020-09-28 |

## Products covered by this Certificate:

| Product Description          | Product Name                                           | Class |
|------------------------------|--------------------------------------------------------|-------|
| X-ray Bone Densitometer      | PRIMUS, DEXXUM T, EXA-3000, EXCELLUS, DEXXUM T Quantum | IIb   |
| Ultrasound Bone Densitometer | SONOST-2000, SONOST 3000, BeeTLe                       | IIa   |

The complete list of devices is filed with the Notified Body

## Sites covered by this certificate

| Site Name          | Address                                                                             |
|--------------------|-------------------------------------------------------------------------------------|
| Osteosys Co., Ltd. | 901~914, 9F, JnK Digitaltower, 111 Digital-ro 26, Guro-gu, Seoul, REPUBLIC OF KOREA |

## EU Representative

CMC Medical Devices & Drugs S.L.  
C/ Horacio Lengo No18, CP 29006, Málaga, Spain

Certificate No.:  
**286016-2019-CE-KOR-NA-PS Rev 5.0**

Project No.:  
**PRJC-595559-2019-MSL-KOR**

Valid Until:  
**17 November 2022**

## Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

## Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

## ● Technical Specification

### General

|                |                                                   |
|----------------|---------------------------------------------------|
| Classification | Internally powered, Class II, Type B Applied part |
|----------------|---------------------------------------------------|

### Device

|                                   |                                                |
|-----------------------------------|------------------------------------------------|
| Model name                        | BeeTLe                                         |
| Dimensions                        | 250 mm x 337 mm x 145 mm                       |
| Weight                            | 3.9 Kg                                         |
| Input Voltage                     | AC 100V ~ 240V, Free Voltage<br>(Single Phase) |
| Frequency                         | 50/60 Hz                                       |
| Power consumption                 | 10 W                                           |
| Battery                           | 3.6V, 6290mAh                                  |
| Ultrasonic Probe Diameter         | Ø25mm                                          |
| Ultrasonic Center Frequency       | 0.5MHz                                         |
| Ultrasonic Probe Position Setting | -                                              |
| Patient's Measurement Posture     | In a sitting posture                           |
| Accessory                         | Daily(QC) Phantom                              |

#### Bluetooth

|                              |                       |
|------------------------------|-----------------------|
| Manufacturer                 | BlueCreation          |
| Model name                   | BC127                 |
| Standard                     | Bluetooth 4.2 Class2  |
| Frequency used and data rate | 2.4GHz / 3Mbps        |
| Sensitivity                  | -88dBm                |
| Operating voltage            | 3.3V ~ 4.7V DC        |
| Dimensions                   | 11.8mm x 18mm x 3.2mm |
| Weight                       | 1.1g                  |

#### NFC

|                        |                                          |
|------------------------|------------------------------------------|
| Manufacturer           | 3ALogics                                 |
| Model name             | NBK-200A                                 |
| Standard               | ISO 14443 B Type / Felica(JIS : X6319-4) |
| Frequency used         | 13.56MHz                                 |
| Communication distance | 5~20mm                                   |
| Operating voltage      | 3.3V DC                                  |
| Dimensions             | 65mm x 32mm x 4.5mm                      |

#### GPS

|                      |                         |
|----------------------|-------------------------|
| Manufacturer         | SIERRA WIRELESS         |
| Model name           | XA1100                  |
| Receive sensitivity. | -165dBm                 |
| Operating voltage    | 3.3V DC                 |
| Dimensions           | 12.5mm x 12.5mm x 6.8mm |



**OsteoSys**

better products for better life

New portable QUS for everyone

# Beetle



3.8kg



5Sec.



NFC



Bluetooth

- Portable wireless QUS(Quantitative Ultrasound) bone mineral densitometer
- Compact size, utmost lightness and enough space for calcaneus measurement
- Connected to mobile phone by bluetooth
- Easiest & quickest measurement with one-touch
- Efficient result reporting and data exporting by special app.
- Multi battery system : Built-in battery interchangeable with backup battery( $\geq 5V$ , 2A)
- Temperature compensation function
- LED and audio guidance





BeeTLe is the one and only QUS bone mineral densitometer with NFC and Bluetooth functions. The measurement can be briefly done by one-touch, and the whole measuring process is operated by BeeTLe's special app. on your mobile phone.



3.8 kg



5Sec.



NFC



Bluetooth

- QUS(Quantitative Ultrasound)
- Measurement site : Calcaneus
- Measurement time : 5 sec.
- Reproducibility : BUA -  $\leq 1.5\%$  C.V.  
SOS -  $\leq 0.2\%$  C.V.  
BQI -  $\leq 1.5\%$  C.V.
- Measured parameter : T-score, Z-score, BQI, BUA, SOS,  
Ratio of T-score and Z-score
- Pediatrics / Trend report / DICOM & PACS
- NFC / Bluetooth / App. / LED & Sound
- Dimension : 249 × 337 × 146 mm
- Weight : 3.8 kg



**OsteoSys**

**OsteoSys Co., Ltd.**

9F, 903 JnK Digital Tower, 111 Digital-ro 26, Guro-gu, Seoul, Korea  
Tel. +82.2.6124.5900 Fax. +82.2.6124.5958 www.osteosys.com

OTBT-EN-003 / Printed in Korea

# 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



---

Name: Young-Bok Ahn

Position : President

**OsteoSys**

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

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