## Device identification

<table>
<thead>
<tr>
<th>Commercial name</th>
<th>BIOSTIM</th>
</tr>
</thead>
<tbody>
<tr>
<td>Model</td>
<td>BB-001</td>
</tr>
</tbody>
</table>
| Type            | Bone Growth Stimulator  
|                 | Low Frequency P.E.M.F. generator |
| Manufacturer    | IGEA S.p.A.  
|                 | Via Parmenide, 10/A - 41012 Carpi – ITALY  
|                 | Phone: 059 699600 – Fax: 059 695778 |

## Technical data

| Generator | Input voltage: 11.1 VDC  
|-----------|--------------------------|
|           | Maximum current assumption: 0.300 A  
|           | Maximum input power: 4 W |
| Applied part | Cupper coil with anallergic, biocompatible PVC cover |
| Output signal | Triangular signal  
|               | Frequency = 75Hz ± 5%  
|               | Pulse width = 1300 usec (± 100usec)  
|               | Magnetic field intensity = 20-30 Gauss (peak value) |
| Rechargeable battery | Li-Po Battery – 11,1VDC / 2000mAh (Lithium-ion Polymer) |
| Dimensions and weight (generator+battery) | W x D x H = 70 x 45 x 96 mm // 270gr |

## Standard compliance

- IEC 60601-1 (Medical electrical equipment - Part 1: General requirements for basic safety and essential performance);
- IEC 60601-1-11 (Medical electrical equipment – Part1: General requirements for basic safety and essential performance – Collateral standard : Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment);
- EN 60601-1-2 (Medical electrical equipment - Part 1: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests);
- EN 60601-1-6 (Medical devices – Application of usability engineering to medical devices);
- EN 62304 (Medical device software – Software life-cycle processes)

## Classification IEC 60601-1

Class II with Applied Part Type BF

## Mode of application

- Device with internal electrical supply rechargeable with specified power supply.
- Device for continuous operation not to be used in presence of anesthetic mixes inflammable in contact with air, oxygen and nitrous oxide.
- Device with casing having a degree of protection IP20.

## Environmental conditions of transportation and storage

- Ambient Temperature: -25 to +70 °C
- Relative humidity: 0% to -25°C at 93% at 70°C (non condensing)
- Atmospheric pressure: 700 to 1060 hPa.