


## OSTEOBIT TECHNICAL SHEET

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| <b>TYPE</b>   | Bone Growth Stimulator   |
| <b>MANUFACTURER</b>   | <b>IGEA S.p.A.</b><br>41012 Carpi (MO), Via Parmenide 10/A (ITA), Italy  |
| <b>MODEL</b>  | <b>OSTEOBIT</b>  |
| <b>TECHNICAL DATA</b>   |  |
| <b>Power supply</b>   | Equipment supplied by the internal power source: NiMH rechargeable battery<br>Generator supply voltage : 9 VDC (NiMH battery 150mAh)<br>Max. absorbed current : 0,010 A<br>Generator max. power : 1,0VA<br>External power supply : 100-240 VAC 50-60Hz   |
| <b>Applied Part</b>   | Biocompatible adhesive electrodes supplied by the Manufacturer IGEA  |
| <b>Output signal</b>  | Sinusoidal signal with impulse train:<br>Electrode piloting frequency : 12,5Hz (80 msec)<br>Duty Cycle = 50% (operational time) : 40 msec)<br>Therapeutic signal frequency : 59 KHz +/-5%<br>Therapeutic signal Maximum range : 20 Vpp (effectively 7 V)<br>Charge Impedance validity field : 500 Ω – 7000 Ω (at nominal frequency)<br>Maximum electrode output current = 1500µA (effective value)   |
| <b>Dimensions<br/>Weight</b>                                  | L x W x P = 80 x 100 x 30 mm<br>150 g (generator only)   |
| <b>Classification (EN 60601-1)</b>                            | Class II with Applied Part of Type BF<br>Appliance for continuous use not to be used where there is danger of explosion<br>Equipment supplied by the internal power source<br>Appliance with casing having a degree of protection IP10   |
| <b>Classification Directive 93/42</b>                         | Ila  |
| <b>Standard Compliance</b>                                    | EN 60601-1 (Medical electrical equipment - Part 1: General requirements for basic safety and essential performance);<br>EN 60601-1-2 (Electromagnetic Compatibility);<br>EN 60601-1-6 (Usability);<br>EN 62304 (medical device software);<br>EN 60601-1-11 (Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment);<br>Medical Device Directive 93/42/CEE e Amending Directive 2007/47/EC |
| <b>Mark</b>   |  0051   |
| <b>Environmental conditions of transportation and storage</b> | Atmospheric temperature : - 20 / +70 °C<br>Relative humidity : 10 % - 90%<br>Atmospheric pressure : 500 - 1060 hPa   |
| <b>Environmental conditions of use</b>                        | Atmospheric temperature : 0 - 40 °C<br>Relative humidity : 30% - 75%<br>Atmospheric pressure : 700-1060hPa   |

