



**BIOSTIM BB-001 Technical Sheet**

<b>Device identification</b>		
Commercial name	<b>BIOSTIM</b>	
Model	<b>BB-001</b>	
Type	<b>Bone Growth Stimulator</b> Low Frequency P.E.M.F. generator	
Manufacturer	<b>IGEA S.p.A.</b> Via Parmenide, 10/A - 41012 Carpi – ITALY Phone: 059 699600 – Fax: 059 695778	
<b>Technical data</b>		
<b>Generator</b>	Input voltage: 11.1 VDC Maximum current assumption: 0,300 A Maximum input power: 4 W	
<b>Applied part</b>	Copper coil with anallergic, biocompatible PVC cover	
<b>Output signal</b>	Triangular signal Frequency = 75Hz ± 5% Pulse width = 1300 usec (± 100usec) Magnetic field intensity = 20-30 Gauss (peak value)	
<b>Rechargeable battery</b>	Li-Po Battery – 11,1VDC / 2000mAh (Lithium-ion Polymer)	
<b>Dimensions and weight (generator+battery)</b>	W x D x H = 70 x 45 x 96 mm // 270gr	
<b>Standard compliance</b>	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); Medical Device Directive 93/42/EEC and its revised version. 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)	
<b>Classification IEC 60601-1</b>	Class II with Applied Part Type BF	
<b>Classification directive 93/42</b>	Class IIa	
<b>Mark</b>		
<b>Mode of application</b>	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.	
<b>Environmental conditions of transportation and storage</b>	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.	