


**BIOSTIM SPT TECHNICAL SHEET**

<b>TYPE</b>	<b>Bone Growth Stimulator</b> Low Frequency P.E.M.F.
<b>MANUFACTURER</b>	<b>IGEA S.p.A.</b> 41012 Carpi (MO), Via Parmenide 10/A (ITA), Italy
<b>MODEL</b>	<b>BIOSTIM SPT</b>
<b>TECHNICAL DATA</b>	
<b>Power Supply</b>	Input voltage : 100-240 VAC (230VAC) Mains frequency : 50-60Hz Max. absorbed power : 0,100 A Max. output voltage : 10,0VA
<b>Applied Part</b>	Copper Coil with anallergic, biocompatible PVC cover
<b>Output SIGNAL</b>	Impulsive square wave signal with frequency of 75Hz ± 5% Pulse width : 1300 µsec (± 200µsec) Duty Cycle : 10% Pulse Amplitude : 180-220 Vdc Magnetic field intensity: : 20-30 Gauss (peak value)
<b>Dimensions</b> <b>Weight</b>	95 x 40 x 160 mm 245 g (only generator)
<b>Classification (EN 60601-1)</b>	Class II with Applied Part of Type BF Appliance for continuous use not to be used where there is danger of explosion 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); EN 60601-1-2 (Electromagnetic Compatibility); EN 60601-1-6 (Usability); EN 62304 (medical device software); EN 60601-1-11 (Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment); 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 a +70 °c Relative humidity : 10% - 90% Atmospheric pressure : 500 - 1060 hpa
<b>Environmental conditions of use</b>	Atmospheric temperature : 0 - 40 °c Relative humidity : 30% - 75% Atmospheric pressure : 700-1060hpa

