

**I-ONE TECHNICAL SHEET**

<b>TYPE</b>	Medical device for the treatment of inflammatory and degenerative diseases of tissues
<b>NAME</b>	I-ONE
<b>MANUFACTURER</b>	<b>IGEA S.p.A.</b> 41012 Carpi (MO), Via Parmenide 10/A (ITA), Italy
<b>MODEL</b>	<b>CBA-03</b>
<b>TECHNICAL DATA</b>	
<b>Generator</b>	NiMh battery power supply : 9,6 VDC – 900 mAh Maximum current assumption : 0,200 A Maximum input power : 3 W Device with internal electrical power supply to be charged with specified power supply.
<b>Rechargeable battery</b>	Type: NiMH 9.6VDC/900mAh Code IG8AAA900 (8x1,2VDC/900mAh Size AAA)
<b>External Power Supply</b>	Input power : 100 -240VAC – 50/60Hz Output voltage / current : 18 VDC – 1000 mA
<b>Applied Part</b>	Copper Coil with anallergic, biocompatible PVC cover
<b>Output signal</b>	Impulsive signal with frequency of di 75Hz ± 5% Pulse width = 1100 µsec (± 100µsec) Magnetic field intensity = 1,5 ± 0,3 mT (15 ± 3 Gauss – peak value)
<b>Dimensions</b>	L x W x H = 68 x 95 x 38 mm
<b>Weight</b>	Generator: 100 g; Battery: 154 g; Coil: 130 g
<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 IP22
<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>	
<b>Environmental conditions of transportation and storage</b>	Atmospheric temperature : -20 to 45 °C Relative humidity : 30 % to 75 % Atmospheric pressure : 700 to 1060 hPa
<b>Environmental conditions of use</b>	Atmospheric temperature : 0 to 40 °C Relative humidity : 30 % to 75 % Atmospheric pressure : 700 to 1060 hPa

