<table>
<thead>
<tr>
<th>TYPE</th>
<th>Medical device for the treatment of inflammatory and degenerative diseases of tissues</th>
</tr>
</thead>
<tbody>
<tr>
<td>NAME</td>
<td>I-ONE</td>
</tr>
</tbody>
</table>
| MANUFACTURER | IGEA S.p.A.  
41012 Carpi (MO), Via Parmenide 10/A (ITA), Italy |
| MODEL | CBA-03                                                                               |

### TECHNICAL DATA

| **Generator** | 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. |
| **Rechargeable battery** | Type: NiMH 9.6VDC/900mAh Code IG8AAA900  
(8x1.2VDC/900mAh Size AAA) |
| **External Power Supply** | Input power : 100 -240VAC – 50/60Hz  
Output voltage / current : 18 VDC – 1000 mA |
| **Applied Part** | Copper Coil with anallergic, biocompatible PVC cover |
| **Output signal** | Impulsive signal with frequency of 75Hz ± 5%  
Pulse width = 1100 µsec (± 100µsec)  
Magnetic field intensity = 1.5 ± 0.3 mT (15 ± 3 Gauss – peak value) |
| **Dimensions** | L x W x H = 68 x 95 x 38 mm |
| **Weight** | Generator: 100 g  
Battery: 154 g  
Coil: 130 g |
| **Classification (EN 60601-1)** | 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 |
| **Classification Directive 93/42** | IIa |

### Standard Compliance

- 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)

### Mark

![CE mark]

### Environmental conditions of transportation and storage

- Atmospheric temperature: -20 to 45 °C
- Relative humidity: 30 % to 75 %
- Atmospheric pressure: 700 to 1060 hPa

### Environmental conditions of use

- Atmospheric temperature: 0 to 40 °C
- Relative humidity: 30 % to 75 %
- Atmospheric pressure: 700 to 1060 hPa