

## 1.4 EMC (Electromagnetic compatibility)

### 1.5.1 Product classification

The device is an engineering medical device, classify according to the standard GB 4824-2004 "industrial, scientific and medical (II SM) radio frequency electromagnetic equipment harassment the limits and the method of measurement" standard classification, it is belonging to one group Classification B engineering medical equipment. The meaning of this classification as follows:

- a) One set of equipment is defined as all engineering medical equipment intend to produce coupled RF energy due to play to their own function.
- b) The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.

### 1.5.2 Declaration of conformity

The device is made by Hawk company meet the requirements of EN60601-1-2: 2007.

Table 3:Guidance and manufacturers declaration – Electromagnetic Emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the Device should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF emissions CISPR 11	Class B	The device is suitable for use in all facilities, including home and connected directly to the household residential public low-voltage power supply network.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker	Complies	

# USER MANUAL MORCELLATOR


emissions		
IEC 61000-3-2		

Table 4: Guidance and manufacturers declaration: Electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
IMMUNITY test	test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge(ESD) IEC 61000-4-2	±8 kV contact ±8 kV air	±8 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile if floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-6	±1 kV line (s) to line(s) ±2 kV line(s) to earth	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% $U_T$ ( > 95% dip in $U_T$ ) for 0,5 cycle 40% $U_T$ (80% dip in $U_T$ ) for 5 cycles <70% $U_T$ (30% dip in $U_T$ ) for 25 cycles <5% $U_T$ ( > 95% dip in $U_T$ ) for 5 s	<5% $U_T$ ( > 95% dip in $U_T$ ) for 0,5 cycle 40% $U_T$ (80% dip in $U_T$ ) for 5 cycles <70% $U_T$ (30% dip in $U_T$ ) for 25 cycles <5% $U_T$ ( > 95% dip in $U_T$ ) for 5 s	Mains power quality should be that of a typical commercial or hospital environment, if the user of the device requires continued operation during power mains interruptions it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3A/m	0.3A/m	If image distortion occurs, it may be necessary to position the device further from sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.
NOTE: $U_T$ is the a. c. mains voltage prior to application of the test level.			

# USER MANUAL MORCELLATOR

**Table 5: Guidance and manufacturers declaration -- Electromagnetic Immunity**

The Model is intended for use in the electromagnetic environment specified below. The customer should assure that it is used in such an environment.

IMMUNITY test	TEST LEVEL	Compliance level	Electromagnetic environment guidance
Conducted RF IEC 61000-4-6	3 Vrms 150kHz to 80 MHz	3Vrms	Portable and mobile RF communications equipment should be used no closer to any part of Model 006, including cables, than recommended separation distance calculated from the equation applicable to the frequency of the transmitter. <b>Recommended separation distance</b> $d = 1.2 \sqrt{P}$ $d = 1.2 \sqrt{P}$ 80MHz–800MHz $d = 2.3 \sqrt{P}$ 800Hz–2.5GHz
Radiated RF IEC 61000-4-3	3V/m 80 MHz to 2.5 GHz	3V/m	where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacture and $d$ is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup> Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Model 006 is used exceeds the applicable RF compliance level above, the Model 006 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Model 006.

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m.