Manufacturer's declaration
for OSSTELL Beacon

Electromagnetic compatibility (EMC)

- WARNING: The use of cables, accessories other than those specified by the manufacturer may result in increased emission and/or decreased immunity.

Cable / Accessories	Length	Reference
Charging cable – Beacon USB cable type C	1.0 m	Osstell Beacon USB Type A to C charging cable Ref. 100709

Electromagnetic compliance testing	
Standards	**Titles**
EN 60601-1-2:2015	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
300328 v2.1.1:2016-11	Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonized Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU

Manufacturer's declaration – Electromagnetic Emission
The product is suitable for use in a specific electromagnetic environment. The customer and/or the user of the product should assure that it is used in an electromagnetic environment as described below.

Emission Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11	Group 1	The product use RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 16-2-1:2014, Ed.3.0 CISPR 16-2-3:2014, Ed.3.2 ETSI EN 300328 v2.1.1:2016-11	Class B	The product 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 purpose.
Harmonics EN 60601-1-2:2015	Class A (*) (**)	
Flicker EN 60601-1-2:2015	Complies (*) (**)	

(*) Device is handheld and charged from a SELV via supplied USB cable. SELV charging adapter is not supplied, device intended to be charged from a computer or general USB charger. Device is tested with representable power adapters. (GlobTek -GTM96060-0606-1.0, FRIWO - FW8002MUSB/05)
(**) Remark: for devices with power consumption of 75 W to 1000 W only

Manufacturer's declaration – Electromagnetic Immunity

The product is suitable for use in a specific electromagnetic environment. The customer and/or the user of the product should assure that it is used in an electromagnetic environment as described below.

Immunity Test	IEC 60601-Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD) EN 61000-4-2:2009, Ed.2.0	± 8 kV Contact ± 15 kV Air	± 8 kV Contact ± 15 kV Air	There are no specific limitations on floor materials or humidity in the environment in which the device is used.
Radiated RF Immunity EN 61000-4-3:2006+A1+A2, Ed.3.2	10 V/m, 80% AM @ 1 kHz, 80 – 6000 MHz	10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the product, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Typically, do not use wireless transmitters within the patient area, i.e. not closer than 1.5 m from the patient when the device is used to measure implant stability. Recommended minimum separation distance: $d = 0.6\sqrt{P}$, where P is the maximum output power rating of the transmitter in Watt (W) according to the transmitter manufacturer and d is the absolute minimum re-commended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey a, should be less than the compliance level. Interference may occur in the vicinity of equipment marked with the following symbol 
Wireless Proximity Test EN 61000-4-3:2006+A1+A2, Ed.3.2	According to Table 9 in EN 60601-1-2:2015, 9 - 28 V/m	10 V/m	
Conducted RF Immunity EN 61000-4-6:2014, Ed.4.0	6 Vrms, 80% AM @ 1kHz, 150 kHz to 80 MHz	6 Vrms, see (*) on previous page.	
Electric Fast Transients Immunity EN 61000-4-4:2012, Ed.3.0	+/- 2 kV, 100 kHz repetition rate	+/- 2 kV, 100 kHz repetition rate	Mains power quality should be that of a typical commercial and/or hospital environment. See (*) on previous page.
Surge Immunity EN 61000-4-5:2014, Ed.3.0	+/- 1 kV	+/- 1 kV	Mains power quality should be that of a typical commercial and/or hospital environment. See (*) on previous page.
Magnetic Fields Immunity EN 61000-4-8:2010, Ed.2.0	30 A/m 50 Hz	30 A/m 50 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Supply Dips Immunity EN 61000-4-11:2004, Ed.2.0	0-315º; each 45: 30% dip, 230V, 25 cy 30% dip, 100V, 25 cy >95% dip, 230V, 0.5 cy >95% dip, 100V, 0.5 cy 100% dip, 230V, 250 cy 100% dip, 100V, 250 cy	As the IEC 60601-Level	Mains power quality should be that of a typical commercial and/or hospital environment. See (*) on previous page.