EUROPEAN DECLARATION OF CONFORMITY

This is a declaration of conformity made under Council Directive 1999/5/EC of 9 March 1999 concerning radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity and Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

The Manufacturer hereby declares, under its sole responsibility, that:

Manufacturer's name:	BLUETENS LIMITED
Business address:	UNIT 905, 9/F, Kowloon center 33 Ashley road, Tsimshatsui Kowloon, Hong-Kong
Trade name:	BLUETENS
Product name:	Bluetens
Type :	BLT15
Product class :	2 a
Scope of application:	Products to which the verification procedure applies, this includes all batches or serial numbers.

Each kind of device or batch of devices complies with the essential requirements and other relevant requirements of the R&TTE Directive (1999/5/EC) and the Medical Devices Directive (93/42/EEC) together with ROHS 2011/65/EU directive. This declaration is being made in conformity with the following standards and/or other normative documents:

Health & Safety:	IEC60601-1, IEC60601-1-11\IEC60601-2-10, IEC 60601-1-1-2: 2007, EN 60601-1-2:2007, AC:2010
EMC:	IEC60601-1-2, EN 301 489-1 V 1.9.2(2011-09), EN 301 489-17 V2.2.1(2012-09)
Spectrum:	EN 300 328 V1.8.1
Other:	EN 62479:2010, ROHS
Attachment:	**European conformity assessment certificate under Annex III of the Directive 93/42/EEC G2 16 05 95243 002**

Authorised signatory:

Signature

DELAHODDE CYRILLE, DIRECTOR — 2016.11.07

Name, Position — Date