EC Declaration of Conformity Tellus 5

Manufacturer	Jabbla b.v.b.a. Foreestelaan 3 B-9000 Gent Belgium
Represented by	Mr. Bart Noé Director
Device group	Alternative and Augmentative communication devices
Description	Dynamic display speech generating device for Augmentative and Alternative Communication (AAC)

Jabbla b.v.b.a. declares that the Tellus 5 conforms to the relevant provisions of the EC Council Directives:

Medical Devices Directive 93/42/EEC according the following harmonised standards:

EN 980:2008	Symbols for use in the labelling of medical devices
EN 5509:1998	User manuals, Contents, structure, formulation and presentation
EN 60601-1:2005	Medical electrical equipment Part 1: General requirements for basic safety and essential performance
EN 60601-1-1:2000	Medical electrical equipment Part 1-1: General requirements for safety Collateral standard: Safety requirements for medical electrical systems
EN 60601-1-2:2007	Medical electrical equipment. Part 1-2: General requirements for basic safety and essential performance. Collateral standard: Electromagnetic compatibility. Requirements and tests
EN ISO 13485:2003	Medical devices Quality management systems Requirements for regulatory purposes
EN ISO 14971:2007	Medical devices Applications of risk management to medical devices

Electromagnetic Compatibility Directive 2004/108/EC according the following harmonised standards:

EN 60601-1-2:2007	Emission according Medical Device Directive Group 1 Class A
EN 55022	(30 MHz … 5 GHz) Class B Radiated Emission Enclosure Port
EN 55011	Class B Conducted Emission AC port
EN 61000-3-2:2006 + A1:2009 + A2:2009	Harmonic Current Emissions
EN 61000-3-3:2008	Voltage Changes, fluctuations and Flicker
EN 60601-1-2:2007	Immunity according (Medical Device Directive) Group 1 Class A
EN 61000-4-2:2009	Electrostatic Discharge (contact +/- 2, 4, 6 kV, Air +/- 2, 4, 8 kV)
EN 61000-4-3:2006 + A1:2008 + A2:2010	RF Immunity (80 MHz…1 GHz - 1.4 GHz…2.7 GHz / 10 V/m)
EN 61000-4-3:2006 + A1:2008 + A2:2010	RF Immunity (80 MHz … 2.5 GHz) 3 V/m
EN 61000-4-4:2004 + A1:2010	Electrical Fast Transients
EN 61000-4-5:2006	Surges
EN 61000-4-6:2009	RF Common mode
EN 61000-4-11:2004	Voltage Dips

For the battery charger

EN60601-1-2:2007 + AC:2010
EN61000-3-2:2006+A1:2009+A2:2009 Class A
EN61000-3-3:2008

Low Voltage Electrical Equipment Directive 73/23/EEC according the following harmonised standards:

The Directive applies to all electrical equipment designed for use with a voltage rating of between 50 and 1000 V for alternating current and between 75 and 1500 V for direct current. Voltage ratings refer to the voltage of the electrical input or output, not to voltages that may appear inside the equipment.

Battery operated equipment outside the voltage rating is obviously outside the scope of the LVD. Nevertheless, any accompanying battery-charger as well as equipment with integrated power supply unit within the voltage ranges of the Directive are in the scope of the LVD. This applies also, in the case of battery operated equipment with supply voltage rating under 50 V AC and 75 V DC, for their accompanying power supply unit.

The Tellus 5 is a battery operated device with no integrated power supply unit within the voltage ranges of the Directive. The input (19 V) and output voltages (5 V) are below 50 V. Therefor the LVD Directive will be applied to stand alone battery charger.

EN60601-1:2006	2006/95/EC (Low Voltage Directive)

Radio Equipment & Telecommunications Terminal Equipment (R&TTE) Directive 1995/5/EC according the following harmonised standards:

Emission	EN 301 489-1:V1.9.2
	EN 301 489-17:V2.1.1
	EN 301 489-7 V1.3.1
Immunity	EN 301 489-1:V1.9.2
	EN 301 489-17:V2.1.1
	EN 301 489-7 V1.3.1

For Telit HE910

Health & Safety (R&TTE art. 3.1a)	EN 60950-1:2006+ A11:2009+ A1:2010 + A12:2011
EMC (R&TTE art. 3.1b)	EN 301 489-1 V1.8.1
	EN 301 489-3 V1.4.1
	EN 301 489-7 V1.3.1
	EN 301 489-24 V1.5.1
RF spectrum use (R&TTE art. 3.2)	EN 300 440-2 V1.4.1
	EN 301 511 V9.0.2
	EN 301 908-1 V4.2.1
	EN 301 908-2 V4.2.1

For Intel Dual Band Wireless-AC 7260

Health and Safety (Art 3(1) (a)):	EN 62368-1: 2014
	EN 62311:2008
EMC (Art.3<1) (b:	EN 301 489-1 v2.2.0 (draft)
	EN 301 489-17 v3 2.0 (draft)
Spectrum (Art.3(2)):	EN 300 328 v2.1,1
	EN 301 893 v1.8-1
	EN 301 893 v2 1.1 (Rx blocking)

Jabbla agrees to develop, implement and maintain a document post-production experience monitoring process, including the notification of reportable events under the European Medical Device Vigilance System Guidelines.

Jabbla, Belgium, April 2018

Bart Noé,
Director