

EU-Type Examination Certificate

Certificate Number: ESTE21-1A Rev: A Date: 2 October 2017
Approval Holder Name: Kyungjin Hong
Suprema Inc.
Approval Holder Address: 17F-5, Parkview Office Tower, 248, Jeongjail-ro, Bundang-gu,
Gyeonggi, 13554 South Korea
Product Name(s): BioStation L2
Product Model(s): BSL2-OM
Brand Name(s): --
Product Manufacturer: Suprema Inc.

Essential Requirement	Applicable Standards / Specifications
Safety Requirements	EN 60950-1: 2006+A11: 2009+A1: 2010+A12: 2011+A2: 2013
EMC Requirements	Draft ETSI EN 301 489-1 V2.2.0 (03/2017); Final draft ETSI EN 301 489-3 V2.1.1(03/2017); EN 55032:2015 Class B ; EN 61000-3-2:2014; EN 61000-3-3:2013; EN 55024:2010+A1:2015; EN 61000-4-2:2009; EN 61000-4-3:2006+A1:2008+A2:2010; EN 61000-4-4:2012; EN 61000-4-5:2014; EN 61000-4-6:2014; EN 61000-4-11:2004
Radio Spectrum	EN 300 330 V2.1.1
RF Exposure Requirements	EN 50364 : 2010

The device shall be marked with the CE mark as shown in accordance with Articles 19 and 20 of the Radio Equipment Directive. (See Annex 2 of this document)

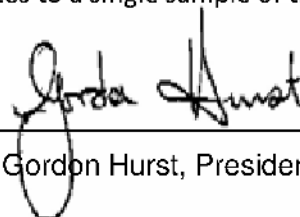


Scope: This EU-Type Examination Certificate is given in respect of compliance of radio spectrum use Article 3 Paragraph 2 of the RED Directive 2014/53/EU. The scope of the evaluation and this certificate relates only to those items identified in "Annex 1 to EU-Type Examination Certificate" for the specific product and Certificate number referenced above.

EU Type Examination was performed according to Module B: EU-type examination procedure per Annex III the Directive on the essential requirements in Article 3, for the specific product and Certificate Number referenced above.

This EU Type Examination Certificate is based upon the review of the Technical Documentation and supporting evidence for the adequacy of the technical design solution, it is only valid in conjunction with the attached Annexes. The scope of this statement relates to a single sample of the apparatus identified above and of the submitted documents only.

Signed by: Gordon Hurst, President & CEO



Annex 1 to EU-Type Examination

EU-Type examination on the essential requirements Article 3

1 a) Health and Safety	Assessed
1 b) Electromagnetic compatibility	Assessed
2 Effective use of radio spectrum	Assessed
3 a) interworks with Accessories/Chargers	Assessed
3 b) interworks with Radio Networks	Assessed
3 c) can connect to interfaces	Assessed
3 d) does not harm the network, misuse network resources.	Assessed
3 e) privacy protections	Assessed
3 f) fraud protections	Assessed
3 g) emergency services access	Assessed
3 h) assist users with disabilities	Assessed
3 i) integrity of software	Assessed

Description of Apparatus

Product Name	BioStation L2
Model Number	BSL2-OM
Brand name	--
Intended use	SRD
Frequency band(s)	13.56 MHz
Operating frequency(s)	13.56 MHz
Number of Channels	1
Channel spacing/ Bandwidth	--
Transmit power	0.39 dBuA/m @ 10m
ITU-class of emission	--
Type of antenna	PCB antenna
Mode of operation	ASK
Duty cycle	--
Notes:	

Technical Construction File Details: (Documents Reviewed)

Test Report(s)

Radio: ESTRCE1706-012
EMC: ESTECE1707-008
ESTECE1707-009
Safety: ESTSCE1603-005
RF Exposure requirements: ESTRCE1706-012(1)

Supporting Documentation

Technical documentation DoC
including: Block Diagram
Bill of Materials
Schematics
Operational Description
PCB Layout / Placement
External Photos
Internal Photos
User Manual
Test Setup Photos
Label
Risk Assessment

Annex 2 to EU-Type Examination Obligations of the Applicant

Ref RED 2014/53/EU Article 10 Obligations of manufacturers

1. When placing their radio equipment on the market, manufacturers shall ensure that it has been designed and manufactured in accordance with the essential requirements set out in Article 3.
2. Manufacturers shall ensure that radio equipment shall be so constructed that it can be operated in at least one Member State without infringing applicable requirements on the use of radio spectrum.
3. Manufacturers shall draw up the technical documentation referred to in Article 21 and carry out the relevant conformity assessment procedure referred to in Article 17 or have it carried out. Where compliance of radio equipment with the applicable requirements has been demonstrated by that conformity assessment procedure, manufacturers shall draw up an EU declaration of conformity and affix the CE marking.
4. Manufacturers shall keep the technical documentation and the EU declaration of conformity for 10 years after the radio equipment has been placed on the market.
5. Manufacturers shall ensure that procedures are in place for series production to remain in conformity with this Directive. Changes in radio equipment design or characteristics and changes in the harmonised standards or in other technical specifications by reference to which conformity of radio equipment is declared shall be adequately taken into account.

When deemed appropriate with regard to the risks presented by radio equipment, manufacturers shall, to protect the health and safety of end-users, carry out sample testing of radio equipment made available on the market, investigate, and, if necessary, keep a register of complaints, of non-conforming radio equipment and radio equipment recalls, and shall keep distributors informed of any such monitoring.

6. Manufacturers shall ensure that radio equipment which they have placed on the market bears a type, batch or serial number or other element allowing its identification, or, where the size or nature of the radio equipment does not allow it, that the required information is provided on the packaging, or in a document accompanying the radio equipment.
7. Manufacturers shall indicate on the radio equipment their name, registered trade name or registered trade mark and the postal address at which they can be contacted or, where the size or nature of radio equipment does not allow it, on its packaging, or in a document accompanying the radio equipment. The address shall indicate a single point at which the manufacturer can be contacted. The contact details shall be in a language easily understood by end-users and market surveillance authorities.
8. Manufacturers shall ensure that the radio equipment is accompanied by instructions and safety information in a language which can be easily understood by consumers and other end-users, as determined by the Member State concerned. Instructions shall include the information required to use radio equipment in accordance with its intended use. Such information shall include, where applicable, a description of accessories and components, including software, which allow the radio equipment to operate as intended. Such instructions and safety information, as well as any labelling, shall be clear, understandable and intelligible.

The following information shall also be included in the case of radio equipment intentionally emitting radio waves:

- (a) frequency band(s) in which the radio equipment operates;
- (b) maximum radio-frequency power transmitted in the frequency band(s) in which the radio equipment operates.

9. Manufacturers shall ensure that each item of radio equipment is accompanied by a copy of the EU declaration of conformity or by a simplified EU declaration of conformity. Where a simplified EU declaration of conformity is provided, it shall contain the exact internet address where the full text of the EU declaration of conformity can be obtained.

10. In cases of restrictions on putting into service or of requirements for authorisation of use, information available on the packaging shall allow the identification of the Member States or the geographical area within a Member State where restrictions on putting into service or requirements for authorisation of use exist. Such information shall be completed in the instructions accompanying the radio equipment. The Commission may adopt implementing acts specifying how to present that information. Those implementing acts shall be adopted in accordance with the advisory procedure referred to in Article 45(2).

11. Manufacturers who consider or have reason to believe that radio equipment which they have placed on the market is not in conformity with this Directive shall immediately take the corrective measures necessary to bring that radio equipment into conformity, to withdraw it or recall it, if appropriate. Furthermore, where the radio equipment presents a risk, manufacturers shall immediately inform the competent national authorities of the Member States in which they made the radio equipment available on the market to that effect, giving details, in particular, of the noncompliance, of any corrective measures taken and of the results thereof.

12. Manufacturers shall, further to a reasoned request from a competent national authority, provide it with all the information and documentation in paper or electronic form necessary to demonstrate the conformity of the radio equipment with this Directive, in a language which can be easily understood by that authority. They shall cooperate with that authority, at its request, on any action taken to eliminate the risks posed by radio equipment which they have placed on the market.

Ref RED 2014/53/EU Article 11 Authorised representatives

1. A manufacturer may, by a written mandate, appoint an authorised representative.

The obligations laid down in Article 10(1) and the obligation to draw up technical documentation laid down in Article 10(3) shall not form part of the authorised representative's mandate.

2. An authorised representative shall perform the tasks specified in the mandate received from the manufacturer. The mandate shall allow the authorised representative to do at least the following:

(a) keep the EU declaration of conformity and the technical documentation at the disposal of national market surveillance authorities for 10 years after the radio equipment has been placed on the market;

(b) further to a reasoned request from a competent national authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of radio equipment;

(c) co-operate with the competent national authorities, at their request, on any action taken to eliminate the risks posed

Article 19 General principles of the CE marking

- 1.The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.
- 2.On account of the nature of radio equipment, the height of the CE marking affixed to radio equipment may be lower than 5 mm, provided that it remains visible and legible.

Article 20 Rules and conditions for affixing the CE marking and the identification number of the notified body

- 1.The CE marking shall be affixed visibly, legibly and indelibly to the radio equipment or to its data plate, unless that is not possible or not warranted on account of the nature of radio equipment. The CE marking shall also be affixed visibly and legibly to the packaging.
- 2.The CE marking shall be affixed before the radio equipment is placed on the market.
- 3.Member States shall build upon existing mechanisms to ensure correct application of the regime governing the CE marking and shall take appropriate action in the event of improper use of that marking.