SmartLinx Neuron 2 Regulatory Notice

Introduction

This Notice contains regulatory information for the SmartLinx Neuron 2 product and is therefore an extension of the *SmartLinx Neuron 2 Installation and Maintenance Guide*. It details the compliance statements that the product requires for its certification and approval. Capsule Technologie is committed to delivering products compliant with standards, laws and regulations.

Certification Marks

c US	Recognized component	CE	Compliance with European directives
c UL us LISTED	Underwriters' Laboratories (USA and Canada)		Separate collection for electrical and electronic waste (WEEE directive and Battery directive)
		FC	Compliance with FCC Regulations

Regulatory compliance and approvals

Canada

Innovation, Science and Economic Development Canada (formerly Industry Canada) Statement

CAN ICES-3 B / NMB-3 B

This device complies with RSS-210 of the Innovation, Science and Economic Development Canada (ISED) Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Caution:

(i) the device for operation in the band 5150-5250 MHz is only for indoor use to reduce the potential for harmful interference to co-channel mobile satellite systems;

(ii) the maximum antenna gain permitted for devices in the bands 5250-5350 MHz and 5470-5725 MHz shall comply with the e.i.r.p. limit; and

(iii) the maximum antenna gain permitted for devices in the band 5725-5825 MHz shall comply with the e.i.r.p. limits specified for point-to-point and non point-to-point operation as appropriate.

(iv) users should also be advised that high-power radars are allocated as primary users (i.e. priority users) of the bands 5250-5350 MHz and 5650-5850 MHz and that these radars could cause interference and/or damage to LE-LAN devices.

Radiation Exposure Statement

This equipment complies with IC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20 cm between the radiator & your body.

European Union

CE Declaration

The SmartLinx Neuron complies with essential requirements and other relevant provisions of the Council Directive 2014/53/EU of April 16, 2014 concerning radio equipment and carry CE-marking accordingly.

This equipment may be operated in:

Austria	Greece	Norway
Belgium	Hungary	Poland
Bulgaria	Iceland	Portugal
Croatia	Ireland	Romania
Cyprus	Italy	Slovakia
Czech Republic	Latvia	Slovenia
Denmark	Liechtenstein	Spain
Estonia	Lithuania	Sweden
Finland	Luxembourg	Switzerland
France	Malta	Turkey
Germany	Netherlands	United Kingdom

Certain countries have specific restrictions for, or prohibitions on devices that operate in the 5 GHz band. Specifically in certain European countries, for example, some frequencies should be restricted to indoor use. You are advised to respect local requirements.

For a copy of the full RED Declaration of Conformity, contact your Capsule Technologie representative.

REACH compliance

Pursuant to REACH regulation 1907/2006, Article 33, and the introduction of Lead in the list of Substances of Very High Concern (SVHC) by the European Chemical Agency (ECHA), Capsule Technologie has identified components in the SmartLinx Neuron 2 containing lead above a 0.1% weight/weight.

Lead is detected in hexagonal stand supporting the main PCB and parts holding the daughter board. These components are internal and consequently does not expose users to the substance. In addition, lead is also detected in the DC connector. This component is made of an alloy that contain a small amount of lead and is not intended to release its substance under normal or reasonably foreseeable conditions of use.

SmartLinx Neuron 2 comply with Directive RoHS 2011/65/EU, as explained in the section, *RoHS and WEEE compliance*.

RoHS and WEEE Compliance

The SmartLinx Neuron does NOT contain any of the following substances (in concentrations exceeding legal threshold limits):

- Lead
- Mercury
- Cadmium
- Hexavalent Chromium
- Polybrominated Biphenyls (PBB)
- Polybrominated Diphenyl Ethers (PBDE)

- Bis(2-Ethylhexyl) phthalate (DEHP)
- Benzyl butyl phthalate (BBP)
- Dibutyl phthalate (DBP)
- Diisobutyl phthalate (DIBP)

In the European Union, SmartLinx Neuron, batteries, and cables should be collected separately and not disposed of with household waste. For details, refer to the section entitled “Disposal” in this document.

Batteries in the SmartLinx Neuron are not based on mercury, lead or cadmium technologies. The batteries used in this product are in compliance with the Council Directive 2006/66/EC.

Chromium, lead, mercury, or cadmium are not intentionally added to packaging materials and are not present in a cumulative concentration greater than 100 ppm as incidental impurities. No halogenated plastics or polymers are used for packaging material. Packaging is compliant with the Council Directive 94/62/EC.

United States

Federal Communications Commission

SmartLinx Neuron complies with Part 15 of the FCC Rules. Operation is subject to two conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause undesired operation.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

Reorient or relocate the receiving antenna.

Increase the separation between the equipment and receiver.

Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

Consult the dealer or an experienced radio/TV technician for help

Note: For operation within 5.15 ~ 5.25GHz / 5.47 ~5.725 GHz frequency range, SmartLinx Neuron 2 is restricted to indoor environment. This device meets the requirements specified in Part 15E, Section 15.407 of the FCC Rules.

Caution: Capsule is not responsible for any radio or television interference caused by unauthorized changes or modifications to this equipment. Unauthorized changes or modifications could void the user’s authority to operate the equipment.

Caution: Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.
This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

Radiation Exposure Statement

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20 cm between the radiator and your body.

Note: The country code selection is for non-US model only and is not available on all US models. Per FCC regulation, all Wi-Fi products marketed in the USA must fixed to US-operation channels only.

Standards and regulations

Field	Standards
Safety	IEC 60950-1 IEC 60601-1 IEC 62133 / UL 2054
EMC	CISPR 22 / CISPR 32 CISPR 24 / CISPR 35 EN 301489-1 / EN 301489-3 / EN 301489-17IEC 60601-1-2 IEC 61000-3-2 / IEC 61000-3-3 IEEE ANSI C63.4
Radio	EN 300328 / EN 300330 / EN 301893 IEEE ANSI C63.10

Essential performance

SmartLinx Neuron complies with EN/IEC 60601-1 and EN/IEC 60601-1-2:

Data Integrity: SmartLinx Neuron does not compromise the data coming from the medical device. This does not include data not being delivered or delays in data delivery.

Medical Device Integrity: SmartLinx Neuron does not compromise the operation of the connected medical devices.

Disposal

As you use the SmartLinx Neuron 2, you will accumulate solid wastes that require proper disposal or recycling. These include system components, batteries, and packaging materials.

Recycling and the Environment

Improper disposal of IT and medical equipment can have a negative impact on health and the environment. We recommend that you dispose of Capsule products, including all electronic devices, cables, batteries, and so on, at an appropriate facility to enable recovery and recycling. You can also recycle packaging and guides according to your local recycling regulations.

In the European Union, for assistance with the recycling of Capsule products, visit our customer site: https://customers.capsuletech.com/environment

Components

At the end of its service life, the the SmartLinx Neuron 2 product, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products. If you have questions concerning disposal of the product, contact Capsule or its representatives.

Batteries

The sealed, rechargeable batteries contain lead and can be recycled. Discharge (deplete) batteries prior to disposal. Place the battery in packaging which electrically isolates its contents. Do not puncture or place the battery in a trash compactor. Do not incinerate the battery or expose it to fire or high temperatures. Dispose in accordance with regional body-controlled guidelines and hospital protocol.

Warning:	Improper disposal of batteries may create an explosion or contamination hazard. Always recycle batteries according to local regulations. Never dispose of batteries in refuse containers. Do not wrap them in metal or aluminum foil. Wrap them in newspaper before disposing of them. Do not burn them. Battery may explode if overheated.

Packaging Material

Retain original packaging materials for future use in shipping the system and its accessories. The recommendation includes corrugated shippers and inserts. Whenever possible, recycle the packaging of accessories and patient applied parts.

Legal Notice

DHF19098

DCN 2017-051