SmartLinx Neuron 3 Regulatory Notice

Introduction

This Notice contains regulatory information for the SmartLinx Neuron 3 product and is therefore an extension of the *SmartLinx Neuron 3 Installation and Maintenance Guide*. It details the compliance statements that the product requires for its certification and approval. Capsule Technologies, Inc. is therefore committed to delivering products compliant with standards, laws and regulations.

Certification Marks

Recognized component

Underwriters' Laboratories

Compliance with FCC Regulations
Assembled from tested components
Complete system not tested

Compliance with European directives

Gulf Mark (G-Mark) for compliance with Gulf Technical Regulation for Low Voltage Electrical Equipment and Appliances.

Compliance with official Mexican standards – NOM (Normas Oficiales Mexicanas).

IATA Lithium Battery Mark Hazard Warning Label (UN 3091)

IATA Lithium Battery Mark Hazard Warning Label (UN 3481)

Regulatory compliance mark (Australia). The SmartLinx Neuron complies with the Radiocommunication Act 1992.

Global Trade Item Number

Compliance for products being placed in Great Britain.

Regulatory compliance and approvals

Canada

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

CAN ICES-003 B / NMB-003 B

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions:

(1) This device may not cause interference.

(2) This device must accept any interference, including interference that may cause undesired operation of the device

Radiation Exposure Statement

This equipment complies with ISED 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.

Caution: The device operates in the band 5150-5350 MHz, for indoor use only.

For further information, contact your local Industry Canada office.

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	

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 3 containing lead above a 0.1% weight/weight.

Lead is detected in hexagonal stands supporting the PCB. 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.

Those parts meet exemptions in Directive RoHS 2011/65/EU, which SmartLinx Neuron 3 complies with 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.

Note: For more information about the Japan RoHS compliance, refer to the website at https://www.capsuletech.com/notices.

Great Britain

The SmartLinx Neuron complies with Radio Equipment Regulations 2017, Electrical Equipment (Safety) Regulations 2016, Electromagnetic Compatibility Regulations 2016 and carries UKCA-marking accordingly.

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

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)

SmartLinx Neuron, batteries, and cables should be collected separately and not disposed of with household waste. For details, refer to Disposal in this document.

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.

Mexico

The SmartLinx Neuron complies with the following Official Mexican Standards − NOM (Normas Oficiales Mexicanas):

- NOM-019-SCFI-1998: Data Processing Equipment – Safety requirements
- NOM-208-SCFI-2016: Products. Radiocommunication systems that employ the dispersed spectrum technique –Radiocommunication equipment − Frequency hopping radiocommunication and digital modulation equipment to operate in the 902 MHz-928 MHz, 2400 MHz-2483.5 MHz and 5725 MHz-5850 MHz-bands − Specifications and test methods

Japan

Ministry of Internal Affairs and Communications (MIC)

The SmartLinx Neuron is certified to the Technical Regulation Conformity Certification under the Japanese Radio Law.

KSA

Communications and Information Technology Commission (CITC)

The SmartLinx Neuron complies with the Wireless Local Area Networks Regulation for the Kingdom of Saudi Arabia.

Singapore

The SmartLinx Neuron is an IMDA (Info-communications Media Development Authority) registered product.

United Arab Emirates

Capsule Technologie, SAS is a TRA registered dealer (DA38012/15).

SmartLinx Neuron is TRA registered equipment:

- SmartLinx Neuron 3 with Port Cover (TA RTTE: ER91900/20)
- SmartLinx Neuron 3 with the 4 Serial+2 USB Ports Connectivity Module (TA RTTE: ER91901/20)
- SmartLinx Neuron 3 with the 7 Serial Ports Connectivity Module (TA RTTE: ER91902/20)

RoHS compliance

Capsule Neuron is compliant with UAE.S IEC 62321 and is ESMA registered.

USA

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: This device meets the requirements specified in Part 15E, Section 15.407 of the FCC Rules.

Caution: Capsule Technologies 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.

Disposal

As you use the SmartLinx Neuron 3, 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 Technologies 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.

Components

At the end of its service life, the products described in this manual, as well as their 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 Technologies 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.

Standards Compliance

Field	Standard or regulation
Safety	IEC 60950-1 UL 2054 / IEC 62133 IEC 60601-1
EMC	IEC 60601-1-2 (Class B emission) IEC 61000-3-2 IEC 61000-3-3 CISPR 22 CISPR 32 CISPR 24 CISPR 35 IEEE ANSI C63.4
Radio	IEEE ANSI C63.10

Essential Performance

- The system maintains clinical data integrity up to delivery to a third-party system. This performance does not include: data not being delivered or the delay of data delivery.
- The system does not compromise the operation of connected medical devices (vital signs monitors).

Legal Notice

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