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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. Philips is therefore committed to delivering products compliant with standards, laws and regulations.

Certification Marks

Australia Regulatory Compliance Mark (RCM). Compliance with Australian Communications and Media Authority (ACMA) / Electromagnetic Compatibility (EMC) regulatory arrangement

Compliance with European directives

FCC Declaration of Conformity. Neuron 3 complies with Electromagnetic Emissions limits specified by the US Federal Communications Commission.

Separate collection for electrical and electronic waste (WEEE directive)

NRTL Safety Mark

NRTL Safety Mark (recognized component)

IATA Lithium Battery Mark Hazard Warning Label (UN 3091)

Compliance for products being placed in Great Britain.

Compliance with Taiwanese requirements from the Bureau of Standards, Metrology and Inspection (BSMI)

Taiwanese National Communications Commission (NCC) certification label

South Korean Communications Commission (KCC) certification label

Gulf Conformity mark (G-mark). Compliance to technical regulations of the Gulf Cooperation Council

Global Trade Item Number

IATA Lithium Battery Mark Hazard Warning Label (UN 3481)

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Regulatory Compliance and Approvals

Brazil

Agência Nacional de Telecomunicações (ANATEL)
The SmartLinx Neuron is certified to comply with the technical requirements and regulations established by ANATEL under Brazilian telecommunications laws.

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 5150-5250 MHz, for indoor use only.

For further information, contact your local Industry Canada office.

European Union / European Economic Area (EEA)

CE Declaration

Philips hereby declares that this device complies with essential requirements and other relevant provisions of the Council Directive 2014/53/EU of April 16, 2014 concerning radio equipment and carries 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 Philips representative.

REACH Compliance

REACH (Registration, Evaluation, Authorization, and Restriction of Chemicals, EC No 1907/2006) represents the European Union's regulatory framework for chemical substances. Philips adheres to all the requirements of this regulation and is dedicated to providing customers with information regarding the presence of REACH Substances of Very High Concern (SVHCs). For more information, contact your Philips representative.

WEEE, RoHS Regulations and EU Battery Directive

The SmartLinx Neuron does NOT contain any of the following substances (in concentrations exceeding legal threshold limits from Directive 2011/65/EU and its amendments):

- 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.

Great Britain

This device complies with essential requirements and other relevant provisions of the 2017 Radio Equipment Regulations, No. 2017 SI 2017/1206. This equipment may be operated in the 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 UKCA Declaration of Conformity, contact your Philips representative.

RoHS and WEEE Compliance

This device 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.

Japan

Ministry of Internal Affairs and Communications (MIC)

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

South Korea

Korea Communications Commission (KCC)

The SmartLinx Neuron is certified to comply with the technical requirements for electromagnetic compatibility (EMC) and telecommunications equipment under South Korean regulation

Singapore

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

United Arab Emirates

Smartlinx Neuron 3 is an equipment registered with the TDRA (Telecommunications and Digital Government Regulatory Authority). For additional details, scan the QR code on the TDRA label located on the product packaging.

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: Philips 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.

Taiwan

Bureau of Standards, Metrology and Inspection (BSMI)

SmartLinx Neuron 3 is BSMI certified and bears the BSMI logo.

The device does not contain any of the substances listed in the table below in percentage exceeding the limits defined in CNS 15633 standard.

設備名稱：醫療平板，型號（型式）：
SL-NU3-UMPC-IOCOVER
SL-NU3-UMPC-IOM7S

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SL-NU3-UMPC-IOM4S2U SL-NU3-UMPC-IOM4S2E						
單元Unit	限用物質及其化學符號					
	鉛Lead (Pb)	汞Mercury (Hg)	鎘Cadmium (Cd)	六價鉻 Hexavalent chromium (Cr^{+6})	多溴聯苯 Polybrominated biphenyls (PBB)	多溴二苯醚 Polybrominated diphenyl ethers (PBDE)
電路板	○	○	○	○	○	○
外殼	○	○	○	○	○	○
玻璃面板	○	○	○	○	○	○
配件	○	○	○	○	○	○

備考1.〝超出0.1 wt %〞及〝超出0.01 wt %〞係指限用物質之百分比含量超出百分比含量基準值。

備考2.〝○〞係指該項限用物質之百分比含量未超出百分比含量基準值。

備考3.〝-〞係指該項限用物質為排除項目。

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 Philips 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 your Philips representative.

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.

Safety and Regulatory Compliance Table

Field	Standard or regulation
Medical device safety	EN 60601-1 IEC 60601-1 3rd edition with national deviations for USA and Canada
IT safety	IEC 62368-1
Medical device usability	IEC 60601-1-6 IEC 62366
Medical device Software – Software Lifecycle Processes	IEC 62304
EMC/EMI	FCC 47 CFR Part 15 sub-part B ICES-003 A / NMB-003 A EN 60601-1-2 CISPR 32/EN 55032 CISPR 35/EN 55035 IEC 61000-3-2 IEC 61000-3-3
Radio	EN 301 489-1 EN 301 489-17 EN 301 893 EN 300 328 EN 300 440 EN 62311 EN 50665 FCC 47 CFR 15 C FCC 47 CFR 15 E
Environment/Packaging	EU Directive 94/62/EC
Environment	REACH 1907/2006
RoHS	EU Directive 2011/65/EU

Field	Standard or regulation
WEEE	EU Directive 2012/19/EU

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).

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Legal Notice

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