















Philips Axon Regulatory Notice

Introduction

This Notice contains regulatory information for the Philips Axon product and is therefore an extension of the *Philips Axon Instructions for Use*. 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 for products being placed in Great Britain.
	Compliance with European directives		Compliance with Taiwanese requirements from the Bureau of Standards, Metrology and Inspection (BSMI)
	FCC Declaration of Conformity. Axon complies with Electromagnetic Emissions limits specified by the US Federal Communications Commission.		Taiwanese National Communications Commission (NCC) certification label
	Separate collection for electrical and electronic waste (WEEE directive)		Compliance with requirements from the Independent Communications Authority of South Africa (ICASA)
	NRTL safety mark		Gulf Conformity mark (G-mark). Compliance to technical regulations of the Gulf Cooperation Council
	South Korean Communications Commission (KCC) certification label		China Quality Certification (CQC) certification label



Regulatory compliance and approvals

Brazil

Philips Axon is an ANATEL (Agencia Nacional de Telecomunicações) certified product.

China

Philips Axon is a CQC (China Quality Certification) certified product.

Philips Axon is a SRRC (State Radio Regulatory Commission) certified product.

Canada

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

CAN ICES-003 B / NMB-003 B

This device contains license-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's license-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 a minimum distance of 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 / 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, this product and its cables should be collected separately and not disposed of with household waste. For details, refer to the section entitled *Recycling and the environment* in this document.

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)

Cables should be collected separately and not disposed of with household waste. For details, refer to the section entitled *Recycling and the environment* in this document.

Japan

Ministry of Internal Affairs and Communications (MIC)

Philips Axon is certified to the Technical Regulation Conformity Certification under the Japanese Radio Law.

Singapore

Philips Axon is an IMDA (Info-communications Media Development Authority) registered product.

South Korea

Philips Axon is a KCC (South Korean Communications Commission) certified product.

Taiwan

Philips Axon contains a NCC (National Communications Commission) certified wireless module.

Philips Axon is BSMI (Bureau of Standards, Metrology and Inspection) 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：數位處理單元，型號 (型式)：						
Philips Axon 120						
Philips Axon 420						
Philips Axon 421						
Philips Axon 820						
限用物質及其化學符號						
單元 Unit	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	○	○	○	○	○	○
<p>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。</p> <p>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。</p> <p>備考3. “-” 係指該項限用物質為排除項目。</p>						

United Arab Emirates

Philips Axon 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

Philips Axon 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 a minimum distance of 20 cm between the radiator and your body.

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

Disposal

As you use the Axon, 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 equipment can have a negative impact on health and the environment. We recommend that you dispose of the Axon, DIM, and serial cables 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 this product, visit our customer site: <https://customers.capsuletech.com/environment>

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

Field	Standard or regulation
	CISPR 32 CISPR 35 IEC 61000-3-2 IEC 61000-3-3
Radio	EN 301 489-1 EN 301 489-17 EN 301 893 EN 300 328 EN 62311 RSS-210 FCC 47 CFR 15 C FCC 47 CFR 15 E
OET65	ANSI/IEEE C95.1
Environment/Packaging	EU Directive 94/62/EC
Environment	REACH 1907/2006
RoHS	EU Directive 2011/65/EU
WEEE	EU Directive 2012/19/EU

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