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

Certification Marks

	Australia Regulatory Compliance Mark (RCM). The Axon complies with the Radiocommunication Act 1992.
	Compliance with European directives
	Separate collection for electrical and electronic waste (WEEE directive)
	NRTL safety mark
	Compliance for products being placed in Great Britain.

Regulatory compliance and approvals

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 A digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

Note: For operation within 5.180 ~ 5.250GHz / 5.500 ~5.700 GHz frequency range, the Axon is restricted to indoor environment. The band from 5600-5650 MHz will be disabled by the software during the manufacturing and cannot be changed by the end user. This device meets all the other 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 be fixed to US-operation channels only.

Great Britain

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

RoHS compliance

Capsule complies with the restriction of the use of certain hazardous substances in Electrical and Electronic Equipment Regulations 2012 as explained in *RoHS and WEEE compliance* below.

Industry Canada statement

This device complies with RSS-210 of the Industry Canada 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 5180-5250 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 5260-5320 MHz and 5500-5700 MHz shall comply with the e.i.r.p. limit; and

iii. the maximum antenna gain permitted for devices in the band 5500-5700 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 5260-5320 MHz and 5500-5700 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 20cm between the radiator and your body.

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 a component in the Philips Axon containing lead below 0.1% weight/weight. All models of Philips Axons comply with Directive RoHS 2011/65/EU, as explained in the next section (*RoHS and WEEE compliance*).

RoHS and WEEE compliance

The Axon 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)

Philips Axon and cables should be collected separately and not disposed of with household waste. Refer to the section on *Recycling and the environment* for more details.

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

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 Capsule products, 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 CISPR 24 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

Legal Notice

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