SmartLinx Axon Regulatory Notice

Introduction

This Notice contains regulatory information for the SmartLinx Axon product and is therefore an extension of the *SmartLinx 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 SmartLinx Axon complies with the Radiocommunication Act 1992.
	Compliance with European directives
	Separate collection for electrical and electronic waste (WEEE directive)
	Gulf Mark (G-Mark) for compliance with Gulf Technical Regulation for Low Voltage Electrical Equipment and Appliances.
	NRTL safety mark
	Compliance for products being placed in Great Britain.

Regulatory compliance and approvals

Federal Communications Commission

SmartLinx 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.

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.

Great Britain

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

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 SmartLinx Axon containing lead above a 0.1% weight/weight.

Lead is detected in a component of the SmartLinx Axon 110 (SL-AXON110-HW) internal power supply. This component is internal and consequently does not expose users to the substance. Moreover, this component is not intended to release its substance under normal or reasonably foreseeable conditions of use.

SmartLinx Axon 410 (SL-AXON410-HW) and SmartLinx Axon 810 (SL-AXON810-HW) do not contain SVHC.

All of the products listed above comply with Directive RoHS 2011/65/EU, as explained in the next section (*RoHS and WEEE compliance*).

RoHS and WEEE compliance

The SmartLinx 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)

SmartLinx Axons 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 SmartLinx 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
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
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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