

CE-Requirement List

AVAKAS LTD

order number:

2021-123

product:

X-TREME AVAX

page:

1/4

date:

1/9/2021

Requirement Group	Requirement	Req. Category	Documents	Description
Legislation to be listed on the EU Declaration of Conformity (DoC) :	EU DoC - LVD Low Voltage Directive 2014/35/EU	Draft from Bitkom	EU Declaration of Conformity (DoC)	EU Declaration of Conformity. Directive 2014/35/EU of 26 February 2014 relating to the making available on the market of electrical equipment designed for use within certain voltage limits (LVD) (recast)
	EU DoC - Electromagnetic Compatibility (EMC) Directive 2014/30/EU	Draft from Bitkom	EU Declaration of Conformity (DoC)	EU Declaration of Conformity. Directive 2014/30/EU of 26 February 2014 relating to electromagnetic compatibility (EMC) (recast).
	EU DoC - RoHS Directive 2011/65/EU	Draft from Bitkom	EU Declaration of Conformity (DoC)	EU Declaration of Conformity. Directive 2011/65/EU of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).
	EU DoC - Ecodesign Energy-related Products (ERP) 2009/125/EC	Draft from Bitkom	EU Declaration of Conformity (DoC)	EU Declaration of Conformity. Directive 2009/125/EC establishing ecodesign requirements for energy-related products.
Safety of electrical equipment	EN 62368-1:2014	A	Electrical safety - Test report	Audio/video, information and communication technology equipment Part 1: Safety requirements (Successor of EN/IEC 60065 and EN/IEC 60950-1).
	EN 62479:2010	A	Electromagnetic Fields (EMF) - Test report	Assessment of the compliance of low power electronic and electrical equipment with the basic restrictions related to human exposure to electromagnetic fields (10 MHz to 300 GHz)
Electromagnetic Compatibility (EMC)	EN 55032:2015 + A11:2020	A	Electro-Magnetic Compatibility (EMC) - Test report	Electromagnetic compatibility of multimedia equipment - Emission Requirements. (CISPR 32:2015, EQV)
	EN 55035:2017 + A11:2020	A	Electro-Magnetic Compatibility (EMC) - Test report	Electromagnetic compatibility of multimedia equipment - Immunity requirements
	EN 61000-3-2:2014	A	Electro-Magnetic Compatibility (EMC) - Test report	Electromagnetic compatibility (EMC) - Part 3-2: Limits - Limits for harmonic current emissions (equipment input current up to and including 16 A per phase)
	EN 61000-3-3:2013	A	Electro-Magnetic Compatibility (EMC) - Test report	Electromagnetic compatibility (EMC) - Part 3-3: Limits - Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current

Requirement Group	Requirement	Req. Category	Documents	Description
Restricted substances in electrical products	RoHS Directive 2011/65/EU + (EU) 2015/863 (Phthalates)	B1	Restricted hazardous substances (RoHS) - Test report	Directive 2011/65/EU of 8 June 2011 on the restriction of the use of certain hazardous substances (RoHS) in electrical and electronic equipment (EEE). Plus Directive (EU) 2015/863 of 31 March 2015 amending Annex II to RoHS Directive 2011/65/EU as regards the list of restricted substances. Additional restrictions for 4 phthalates: DEHP, BBP, DBP and DIBP. Also known as "RoHS 3" Directive. Including Amending Directive (EU) 2017/2102 of 15 November 2017.
	RoHS Directive 2011/65/EU - Annexes III and IV (Exemptions) 2022-02	G		Annex III to ROHS Directive 2011/65/EU lists the exempted applications to the restricted substances in Annex II. Annex IV lists the exempted applications specific to medical devices and monitoring and control instruments. The following amendments are included in this consolidated version: Directives 2012/50/EU and 2012/51/EU of 10 October 2012 (Annex III); Directives 2014/1/EU to 2014/16/EU of 18 October 2013 (Annexes III and IV); Directives 2014/69/EU to 2014/76/EU of 13 March 2014 (Annexes III and IV); Directives (EU) 2015/573 and (EU) 2015/574 of 30 January 2015 (Annex IV); Directive (EU) 2016/585 of 12 February 2016 (Annex IV); Directives (EU) 2016/1028 and (EU) 2016/1029 of 19 April 2016 (Annex IV); Directives (EU) 2017/1009 to (EU) 2017/1011 of 13 March 2017 (Annex III); Directives (EU) 2018/736 to (EU) 2018/742 of 18 May 2018 (Annex III); Directives (EU) 2019/169 to (EU) 2019/178 of 5 February 2019 (Annex III); Directives (EU) 2019/1845 and (EU) 2019/1846 of 5 November 2019 (Annex III); Directive (EU) 2020/360 of 5 March 2020 (Annex IV); Directive (EU) 2020/361 of 5 March 2020 (Annex III); Directive (EU) 2020/364 of 5 March 2020 (Annex IV); Directive (EU) 2020/366 of 5 March 2020 (Annex IV); Directive (EU) 2021/647 of 15 January 2021 (Annex III); Directive (EU) 2021/884 of 8 March 2021 (Annex IV); Directives (EU) 2021/1978, (EU) 2021/1979 and (EU) 2021/1980 of 11 August 2021 (Annex IV); Directives (EU) 2022/274 to (EU) 2022/284 and (EU) 2022/287 of 13 and 16b December 2021 (Annex III).
	EN IEC 63000:2018	G		Technical documentation for the assessment of electrical and electronic products with respect to the restriction of hazardous substances
Ecodesign	EN 50672:2017	A	Ecodesign - Test report	Ecodesign requirements for computers and computer servers.
	Regulation (EU) 617/2013 - Ecodesign computers, servers (2019)	A	Ecodesign - Test report	Regulation (EU) 617/2013 of 26 June 2013 implementing Directive 2009/125/EC of the European Parliament and of the Council with regard to ecodesign requirements for computers and computer servers. Consolidated version including amendments: Regulation (EU) 2016/2282 of 30 November 2016 and Regulation (EU) 2019/424 of 15 March 2019.

Additional information - relevant for the Technical Documentaion

Requirement Group	Requirement	Req. Category	Documents	Description
Product traceability information	Bill of Materials (BOM)	B3	Bill of Materials (BOM)	Bill of Materials (BOM). The Bill of Material gives an overview of the parts / materials / components required to produce the product. The level of detail shall be sufficient to enable risk assessments of chemical, environmental, physical, electrical, constructional, biological and other hazards.
	Declaration of Identity for the product	B3	Declaration of Identity for the product	Declaration of Product Identity - with this declaration you declare that the related product X is the same as the product mentioned in test documents
	Pictures of the product	B3	Picture of product	Please include here picture(s) of the product. These could be generic pictures that you use to identify the product.
	Product, production reference - Model, type, batch or serial number	B3	Product Labelling - Artwork	It is advised to have a production code - batch code - on a product and on the consumer outer packaging (unless otherwise agreed with your customer and not in conflict with the legal requirements) in order to be able to identify a specific batch in case of an issue in the market. In some cases an "use before date" is applicable. Add your example here.
Product design information	Mechanical drawings or exploded views	B3	Mechanical drawing or exploded view	A mechanical drawing, diagram or a more detailed "exploded view" is used to visualise the design of a product or a component. This ranges from a cable with connectors to complex products. The information is useful for manufacturing and assembly. A drawing showing the separate components can also be helpful for maintenance and identification of spare parts. The parts can be numbered with a reference to the Bill of Materials. It is information to specify the product in sufficient details, it is rarely required by surveillance authorities.
	Printed circuit board (PCB) – Diagrams and layouts	B3	Printed Circuit Board (PCB) layout	Printed circuit board (PCB) – Diagrams and layouts. Add artwork of the PCB layout (tracks, component layout, silk screen). Add drawing or pictures of the assembled PCB. Add circuit diagrams of the PCB design.
	Safety Critical Components List (CCL), Constructional Data (CDF)	B3	Critical components and constructional data (CCL /CDF)	CDF is "Construction Data Form"; this form shows compliance details for the (safety critical) components of a product. CCL is "Critical Components List"; this document lists all critical components. If critical components have a failure then the safety could be breached. Changing one of the critical components may affect the safety of the product. CCL and CDF are often combined and included in test reports.
Markings, labels, information and instructions for use	CE marking	B1	CE marking - Artwork of label	Obligation to affix the CE marking to the product. The CE marking must be affixed visibly, legibly and indelibly to the product or to its data plate. However, where this is not possible or not warranted on account of the nature of the product, it must be affixed to the packaging, if any, and/or to the accompanying documents. The CE marking may not be affixed until the conformity assessment procedure has been completed to ensure that the product complies. In some cases CE marking is also required on the packaging and documentation. New Legislative Framework (NLF) - Regulation (EC) 765/2008 relating to the marketing of products.
	EN 50419:2006 - WEEE symbol	B2	WEEE symbol (Crossed-out wheeled bin) - Artwork of label	Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE) and Annex IX of Directive 2012/19/EU (WEEE 2) Not CE relevant.

Requirement Group	Requirement	Req. Category	Documents	Description
	User information - Manuals and Instructions	B1	User instruction manual	Add here your manual / instruction here. Note that safety related instructions and warnings must be in the language of the country that you are selling the product in!
	User information - Markings, Ratings, Warnings, Pictograms	B1	Product (safety) markings - Artwork	Copy of Markings, Packaging, Rating labels - warning labels / signs. Either labels or engraving. Where relevant also show a picture where and how these markings are applied on the product. Note that warnings and safety instructions must be in the language of the country of sales!
Risk assessments	Hazardous chemicals	RISKS	Risk assessment forms	Risk assessment. Assessment on the hazards of chemical substances (exposure, environment). Bans, restrictions and obligations (registration, notification) related to these substances. Examples: carcinogenic, mutagenic or reproductive toxicant (CMR) substances; persistent, bio-accumulative and toxic (PBT) substances; very persistent and very bio-accumulative (vPvB) substances; endocrine disruptors (EDR); toxics; allergens and other substances of very high concern (SVHC).
	Consumer product safety hazards	RISKS	Risk assessment forms	Risk assessment. Overarching, generic or umbrella approach: protection of the health and safety of users of (consumer) product. Risk assessment taking into account all relevant aspects (design, materials, components, presentation, packaging) for the consumers who are likely to use the products; in particular vulnerable users (children, the elderly and the disabled).
	Electrical hazards	RISKS	Risk assessment forms	Risk assessment. Electrical hazards may cause electrocution, electric shock and expose consumers to other (electrical) energy related risks.
	Electromagnetic hazards	RISKS	Risk assessment forms	Risk assessment. Assessment on two risks: too high emissions causing interference with adjacent equipment and too low immunity (or too high susceptibility) to disturbances resulting in unacceptable degradation of performance.
	Thermal hazards	RISKS	Risk assessment forms	Risk Assessment. Thermal hazards: smoke, fire, explosion, injuries, burns, scalds, injuries, damage to properties caused by flammable materials. Including the hazards of hot / cold (non-)functional surfaces for consumers.