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FAQs for Tender Submissions Regarding Qlicksmart® Devices

The below table sets out suggested wording for frequently asked questions when submitting a tender response which includes Qlicksmart devices. If you require any additional information, please email your Qlicksmart account contact or hello@qlicksmart.com.

Question	*Suggested Answer*
Questions concerning general information about Qlicksmart as the manufacturer.	
Details of the Legal Manufacture of Qlicksmart® devices	Name: Qlicksmart Pty Ltd Address: Level 1, 148 Boundary street, West End QLD 4101, Australia Australian Business Number (ABN): 37 033 096 995
Does Qlicksmart have an accredited Quality Management System in place?	Qlicksmart is certified to ISO 13485:2016 and employs good manufacturing practices to align with international medical device regulations (eg. Australian TGA, Unites States FDA, European MDR 2017:745, UK MDR 2002). A copy of our current ISO 13485:2016 certificate is available via the link here.
Questions concerning Qlicksmart's ethical business practices.	
Does Qlicksmart have a policy in place to eliminate modern slavery/forced labour in the supply chain?	Yes. Qlicksmart's Modern Slavery Policy follows Australian legislated requirements under the *Australian Modern Slavery Act 2018*, as the company is based in Australia. These requirements act in accordance with the UN Declaration of Human Rights, UN Guiding Principles on Business and Human Rights, and ILO Forced Labour Conventions. Qlicksmart's Modern Slavery Policy can be found on the website at: https://www.qlicksmart.com/modern-slavery-policy/.
Does Qlicksmart have a whistle-blower policy in place?	Yes. Qlicksmart complies with whistle-blower protections per Australian legislated requirements. Qlicksmart's whistle-blower policy is included in the Human Resources Manual, which is provided to all employees. Per the Human Resources Manual: *"any employee, who in good faith, raises a complaint or discloses an alleged breach of the above or any concern regarding compliance to the law, whilst following correct reporting procedures, will not be disadvantaged or prejudiced. All reports will be dealt with in a timely and confidential manner."*
Do you have an Ethical Trading / Labour Standards / Supplier Code of Conduct / Responsible Sourcing Policy?	Yes. For internal employees, Qlicksmart complies with legislated requirements under the Australian *Fair Work Act 2009*. All employees are provided with a Human Resources Manual outlining these requirements. All contract manufacturers complete an ethical trading questionnaire as part of the supplier evaluation process.
Have you carried out an ethical trading Risk Assessment on your suppliers?	Yes. All contract manufacturers complete an ethical trading questionnaire as part of the supplier evaluation process.

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Questions concerning sustainability and environmental issues.	
Does Qlicksmart have a Sustainable Packaging policy?	No. However, Qlicksmart has sustainable packaging practices in place and is committed to working with responsible suppliers. These sustainable packing practices include: • Qlicksmart uses recyclable cardboard packaging for individual unit boxes and cartons. Only sterile scalpel blade removers include plastic blister-packaging, which is required for the sterilisation process. • Where possible, Qlicksmart's contract manufacturers utilise recycled materials to reduce the quantity of virgin non-renewable materials being used. • Qlicksmart has actively reviewed all product packaging to ensure that it is limited to what is necessary for safe delivery of device. • No plastic is used by Qlicksmart's warehouses and delivery partners to deliver products to customers. • Instructions are provided via pictorial guides on the existing product packaging and/or provided via a QR code, to eliminate additional paper instructions.
Why are BladeFLASK and BladeFlask EVO made from plastic?	BladeFLASK and BladeFlask EVO are primarily made from Acrylnonitirle Butadiene Styrene (ABS). Due to the sensitive nature of biohazard waste, plastics like ABS are still necessary for optimum safety, as it has a strong resistance to corrosive chemicals and physical impacts. It is also a durable material, which is necessary to maintain its efficacy during a potentially significant product life. BladeFLASK and BladeFlask EVO are both sharps containers, and as such there are device design features which are required by regulations and industry standards. These include: • Made of heavy-duty plastic (FDA) • Resistance to puncture and penetration (ISO 23907:2012, Australian Standard AS 4031:1992) • High impact resistance to damage or leakage (ISO 23907:2012, Australian Standard AS 4031:1992) • Include a handle (ISO 23907:2012, Australian Standard AS 4031:1992) Using ABS as the primary material ensures that the BladeFLASK and BladeFlask EVO meet these requirements. Utilising the BladeFLASK or BladeFlask EVO means that users do not require an additional sharps container after removing scalpel blades in a safe and compliant manner. BladeFLASK and BladeFlask EVO are also manufactured with some recycled plastics, to reduce the amount of virgin non-renewable materials. Qlicksmart has recognised the importance of considering the environmental impact of medical devices, and are committed to

	assessing where improvements can be made across the device's lifecycle to be more sustainable without negative impacts to quality, safety, and infection control.
Why are the single-use scalpel blade removers made from plastic?	Qlicksmart's single-use scalpel blade removers are made from Polypropylene. Due to the sensitive nature of biohazard waste, plastics like Polypropylene are still necessary for optimum safety, as it has a strong resistance to corrosive chemicals and physical impacts. Polypropylene is also the standard material used for single-use medical devices used in surgical settings as it can be sterilised. This is because of the material's ability to withstand high temperatures. Qlicksmart has recognised the importance of considering the environmental impact of medical devices, and are committed to assessing where improvements can be made across the device's lifecycle to be more sustainable without negative impacts to quality, safety, and infection control.
What is Qlicksmart doing to become more environmentally sustainable?	Qlicksmart has established an internal committee to review and improve our environmental sustainability at both a company and product level. Current sustainability implementation projects include: • Consolidation of shipments to reduce emissions from air freight. • Consolidation of stock warehousing to reduce emissions from land freight. • Digitisation of all company records; including Quality Management, accounting, design, and project documentation. • Review of procurement processes to identify potential consolidation of suppliers. • Environmental performance as one of the key criteria for all existing and future R&D processes • Working with contract manufacturers to identify potential areas for improvement across the device's entire product cycle, including testing alternative raw materials. • Working with distributors to consolidate supply of goods in order to reduce emissions from freight. • Working with distributors to provide digital marketing and product training materials to end-users where possible.
Global Warming Potential	Qlicksmart does not currently measure this, nor are required to under Australian or international regulations and guidelines. Qlicksmart is actively reviewing internal business practices and product lifecycles to identify any areas which can be improved for more sustainable practices.
Questions concerning product information.	
What are the specifications of the product?	A summary of the product specifications are included in the relevant product's brochure (on page 3), and are available on the Qlicksmart website. Any further questions concerning product specifications can be sent to Qlicksmart via email at hello@qlicksmart.com.

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What is the country of origin?	The country of origin for all Qlicksmart devices is Malaysia.
What is the shelf-life of the devices?	The shelf-life of Qlicksmart's sterile single-use devices are 5 years from the date of manufacture. The expiry date is listed on the product packaging. This applies to the following devices: • BladeCASSETTE (sterile) • BladeNeedleSYSTEM (sterile) • BladeSINGLE (sterile) Qlicksmart's non-sterile devices are made from sturdy materials, so a shelf-life is not applicable. However, a useful life of 10 years has been defined and approved by Qlicksmart's certified/notified body. This applies to the following devices: • BladeFLASK • BladeFlask EVO • SnapIT • CheckCLIP
What are the regulatory listings for Qlicksmart devices?	Summary is available via this link.
What are the packaging details?	Summary is available via this link.
Where are the instructions?	Qlicksmart devices include pictorial instructions on the product packaging. How to use guides are included in the relevant product's brochure, which are available on the Qlicksmart website. Video guides can also be found on the Qlicksmart YouTube channel via this link.
What material is the device made from?	Device materials are included in the Specifications section of the relevant product's brochure (on page 3), which are available on the Qlicksmart website.
Does the device contain any of the following? - *Latex* - *DEHP* - *PVC* - *Rubber* - *Lubricant* - *Silicone*	No Qlicksmart devices contain Latex, DEHP, PVC, Rubber, or Lubricant. The SnapIT ampoule openers contain an O-Ring which is made from silicone.

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Questions concerning why the devices are unique and/or should be included.	
Why should the BladeFLASK be included in the tender?	The Qlicksmart BladeFLASK is the world's first single-handed scalpel blade remover, and can remove and contain 100 scalpel blades. Key features of the BladeFLASK are: • Single-handed with use of reusable Mounting Bracket • Sharps container: FDA-listed and compliant with ISO 23901.1 and AS 4031:1992 • Engineering Control against sharps injuries caused by scalpels, which occur 12.6 times for every 100,000 scalpel blades purchased. • Passive (automatic) safety mechanism. Passive safety-engineered devices have shown to be more effective at preventing sharps injuries than active (manually operated) devices. • Complies with international sharps safety regulations and guidelines, including the Australian Standard AS 3825:2020 and OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030). • Audible "click" sound and tactile feedback to signify blade is safely contained. • Compatible with most standard surgical scalpel blades and flat handles. It is understood that BladeFLASK and BladeFlask EVO are the only combined single-handed scalpel blade remover and sharps container devices commercially available to remove and contain 100 scalpel blades.
Why should the BladeFlask EVO be included in the tender?	The Qlicksmart BladeFlask EVO is the next-generation model of the BladeFLASK, which removes and contains 100 scalpel blades. Key features of the BladeFlask EVO include: • Single-handed with use of reusable Mounting Bracket • Sharps container: FDA-listed and compliant with ISO 23901.1 and AS 4031:1992 • Engineering Control against sharps injuries caused by scalpels, which occur 12.6 times for every 100,000 scalpel blades purchased. • Patented passive (automatic) safety mechanism. Passive safety-engineered devices have shown to be more effective at preventing sharps injuries than active (manually operated) devices. • Complies with international sharps safety regulations and guidelines, including the Australian Standard AS 3825:2020 and OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030). • Audible "click" sound and tactile feedback to signify blade is safely contained. • Compatible with standard surgical blades, Post Mortem blades, flat handles, hexagonal handles, circular handles, Baron handles, and Post Mortem (bulbous) handles.

	It is understood that BladeFLASK and BladeFlask EVO are the only combined single-handed scalpel blade remover and sharps container devices commercially available to remove and contain 100 scalpel blades.
Why should the Qlicksmart BladeCASSETTE and BladeSINGLE be included in the tender?	Qlicksmart's BladeCASSETTE and BladeSINGLE scalpel blade removers safely remove and contain scalpel blades in surgical settings. Key features include: • Single-handed • Sterile – available off-the-shelf or within surgical procedure packs. • Engineering Control against sharps injuries caused by scalpels, which occur 12.6 times for every 100,000 scalpel blades purchased. • Patented passive (automatic) safety mechanism. Passive safety-engineered devices have shown to be more effective at preventing sharps injuries than active (manually operated) devices. • Complies with international sharps safety regulations and guidelines, including the Australian Standard AS 3825:2020 and OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030). • Audible "click" sound and tactile feedback to signify blade is safely contained. • Transparent Cartridges which contain the scalpel blades, to ensure an easy count. • Compatible with standard surgical blades, flat handles, hexagonal handles, circular handles, and Baron handles. • BladeSINGLE removes and contains 1 scalpel blade, and is ideal for minor procedures. • BladeCASSETTE removes and contains 3 scalpel blades, and is ideal for most procedures. It is understood that outside the Qlicksmart range, there are no other single-handed scalpel blade removal and containment devices commercially available for use in sterile settings.
Why should the Qlicksmart BladeNeedleSYSTEM be included in the tender?	Qlicksmart's BladeNeedleSYSTEM combines a needle counter with a scalpel blade removal device to safely remove and contain sharps in surgical settings. Key features include: • Single-handed • Sterile – available off-the-shelf or within surgical procedure packs. • Engineering Control against sharps injuries caused by scalpels, which occur 12.6 times for every 100,000 scalpel blades purchased. • Patented passive (automatic) safety mechanism. Passive safety-engineered devices have shown to be more effective at preventing sharps injuries than active (manually operated) devices. • Complies with international sharps safety regulations and guidelines, including the Australian Standard

	AS 3825:2020 and OSHA Bloodborne Pathogens Standard (29 CFR 1910.1030). • Audible “click” sound and tactile feedback to signify blade is safely contained. • Transparent Cartridges which contain the scalpel blades, to ensure an easy count. • Compatible with standard surgical blades, flat handles, hexagonal handles, circular handles, and Baron handles. • Removes and contains 2 scalpel blades, which is ideal for general surgeries. • 20-count foam standard needle counter, for suture needles. • High density foam to safely secure suture needles • Secure closing latch. • Extra deep lid (2cm) to accommodate wide range of suture needles. • Magnetic strip can be used for non-regular sized sharps. It is understood that outside the Qlicksmart range, there are no other single-handed scalpel blade removal and containment devices commercially available for use in sterile settings. BladeNeedleSYSTEM is the only commercially available needle counter which also contains the scalpel blade at removal to prevent downstream injuries.
Why should the Qlicksmart ampoule openers be included in the tender?	Qlicksmart’s SnapIT ampoule opener range help users open ampoules quickly and safely. Key features include: • Reusable. Only the silicone O-Ring requires replacement over time, and O-Ring replacements are available at a low-cost. • Long product life. SnapIT ampoule openers are made from sturdy materials, which results in a long product life which is sustainable and cost-effective. • Engineering Control against sharps injuries caused by ampoules, which are common among nurses and anaesthetists. • Facilitates a clean break of ampoule neck, preventing spills and glass contamination. • Easily disassembled for cleaning in line with infection control requirements. • Available in multiple sizes for compatibility to most ampoules. • SnapIT Personal and SnapIT Trolley models are made with anodised aluminium, and are autoclavable up to 130° Celsius. SnapIT was tested against five other ampoule opening devices and found to be the easiest to use while meeting safety criteria. Link to case study by a USA laboratory here.

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