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Qlicksmart® Devices Regulatory Summary

GENERAL

Product	Product Code	GMDN Code	Material	Latex	DEHP	Sterile	Method of sterilization	Re-usable	EAN Number	Packaging	International Standards (ISO) used for conformity assessment:
BladeFLASK	QFYGEN (yellow) QFRGEN (red) QFYUKGEN (UK label)	46235	Body: ABS (Acrylonitrile Butadiene Styrene) Inner mechanism: Polyacetal (POM), Stainless and Hardened Steel	No	No	No	–	Single-use sharps container; unit removes up to 100 blades	Yes	Independently tested by a NATA accredited laboratory in accordance with the provisions of the United Nations Transport of Dangerous Goods, Chapter 6	ISO23901.1 - Sharps Injury Protection
BladeFlask EVO	QBVYGEN (yellow) QBVRGEN (red) QBVYUKGEN (UK label)	46235	Body: ABS (Acrylonitrile Butadiene Styrene) Inner Mechanism: ABS and Stainless Steel	No	No	No	–	Single-use sharps container; unit removes up to 100 blades	Yes	Independently tested by a NATA accredited laboratory in accordance with the provisions of the United Nations Transport of Dangerous Goods, Chapter 6	ISO23901.1 - Sharps Injury Protection
BladeCASSETTE	QSSVCAS-3Y (yellow) QSSVCAS-3R (red)	46236	Polypropylene (PP)	No	No	Yes	Gamma	Single-use; unit removes up to 3 blades	Yes	–	The Australian Standard 3825:2020, Procedures and devices for the removal, containment, and disposal of scalpel blades from scalpel handles

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BladeNeedleSYSTEM	QBN202S (yellow) QBNS202R (red)	46236	Needle counter box: High Impact Polystyrene Cartridges: Polypropylene (PP)	No	No	Yes	Gamma	Single-use; unit removes up to 2 blades	Yes	–	The Australian Standard 3825:2020, Procedures and devices for the removal, containment, and disposal of scalpel blades from scalpel handles
BladeSINGLE	QSBS01	46236	Polypropylene (PP)	No	No	Yes	Gamma	Single-use	Yes	–	The Australian Standard 3825:2020, Procedures and devices for the removal, containment, and disposal of scalpel blades from scalpel handles
SnapIT Personal	SN-01Rb (Blue) SN-01Rp (Purple)	10098	Body: Aluminium Spring and keyring: Stainless Steel O-Ring: Silicon	No	No	No	–	Multi-use	Yes	–	–
SnapIT Trolley	TE-01R (Regular) TE-01L (Large) TE-01XL (Extra Large)	10098	Body: Aluminium Spring and keyring: Stainless Steel O-Ring: Silicon	No	No	No	–	Multi-use	Yes	–	–
SnapIT Lite	SN-02R (Regular grey) SN-02Rb (Regular blue)	10098	Body: ABS (Acrylonitrile Butadiene Styrene) Spring and keyring: Stainless Steel	No	No	No	–	Multi-use	Yes	–	–

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	SN-02Rpp (Regular purple) SN-02Rpk (Regular pink) SN-02L (Large)		O-Ring: Silicon								
CheckCLIP	QSCCVIAL (For vial) QSCCGEN (For ampoule)	46240	Polypropylene (PP)	No	No	No	–	Single-use	Yes	–	–

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UNITED STATES

Product	FDA device listing (hyperlinked)	FDA Classification Name	Device Class	510(k) Number	Product Code	Regulation Number	Enables compliance with standard
BladeFLASK	Qlicksmart BladeFLASK is FDA 510(K) premarket approved (# K983367) as a sharps container.	container, sharps	II	K983367	MMK	880.5570	OSHA's Bloodborne Pathogens standard – CFR 1910.1030
BladeFlask EVO	Qlicksmart BladeFlask EVO is FDA 510(K) premarket approved (# K213274) as a sharps container.	container, sharps	II	K213274	MMK	880.5570	OSHA's Bloodborne Pathogens standard – CFR 1910.1030
BladeCASSETTE	Qlicksmart BladeCASSETTE is FDA listed.	Blade, Scalpel	I	-	GES	878.4800	OSHA's Bloodborne Pathogens standard – CFR 1910.1030
BladeNeedleSYSTEM	Qlicksmart BladeNeedleSYSTEM is FDA listed.	Blade, Scalpel	I	-	GAB	878.4800	OSHA's Bloodborne Pathogens standard – CFR 1910.1030
BladeSINGLE	Qlicksmart BladeSINGLE is FDA listed.	Blade, Scalpel	I	-	GES	878.4800	OSHA's Bloodborne Pathogens standard – CFR 1910.1030
SnapIT	Qlicksmart SnapIT is FDA listed.	Surgical, General Use	I	-	MDM	878.4800	-
CheckCLIP	Qlicksmart CheckCLIP is FDA listed.	Labelling	I	-	LYV	878.4800	-

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EU

Product	Classification Rule	Measuring Function	Which European regulation have been used for conformity assessment?	CE Compliant/ Marked	European Representative	Italian Reportoire Number	Notified Body	Notified Body Details	Notified Body Identification Number
BladeFLASK	Class I	No	Annex IV of Medical Device Regulation (EU) 2017/745 Annex IX (as modified by part II of schedule 2A to the UK MDR 2002)	Yes	Donawa Lifescience , Piazza Albania 10, 00153 Rome, Italy, P.IVA o VAT Number 10442731005	340114	No	–	–
BladeFlask EVO	Class I	No	Annex IV of Medical Device Regulation (EU) 2017/745 Annex IX (as modified by part II of schedule 2A to the UK MDR 2002)	Yes	Donawa Lifescience , Piazza Albania 10, 00153 Rome, Italy, P.IVA o VAT Number 10442731005 10442731005	340114	No	–	–
BladeCASSETTE	Class I Sterile	No	Annex V of Directive 93/42/EEC as amended by Directive 2007/47/EC	Yes	Donawa Lifescience Consulting Srl, Piazza Albania 10, 00153 Rome, Italy, P.IVA o VAT Number 10442731005	340117	Yes	TÜV SÜD Product Service GmbH	0123

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Product	Classification Rule	Measuring Function	Which European regulation have been used for conformity assessment?	CE Compliant/ Marked	European Representative	Italian Reportoire Number	Notified Body	Notified Body Details	Notified Body Identification Number
BladeNeedleSYSTEM	Class I Sterile	No	Annex V of Directive 93/42/EEC as amended by Directive 2007/47/EC	Yes	Donawa Lifescience Consulting Srl, Piazza Albania 10, 00153 Rome, Italy, P.IVA o VAT Number 10442731005	1399879	Yes	TÜV SÜD Product Service GmbH	0123
BladeSINGLE	Class I Sterile	No	Annex V of Directive 93/42/EEC as amended by Directive 2007/47/EC	Yes	Donawa Lifescience Consulting Srl, Piazza Albania 10, 00153 Rome, Italy, P.IVA o VAT Number 10442731005	1399874	Yes	TÜV SÜD Product Service GmbH	0123
SnapIT	Not Applicable; not a medical device in Europe	-	-	-	-	-	Not Applicable	-	-
CheckCLIP	Not Applicable; not a medical device in Europe	-	-	-	-	-	Not Applicable	-	-

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AUSTRALIA

Product	TGA ARTG No	Compliant Standards for scalpel blade removal	Which Australian Standards for sharps containers have been used for conformity assessment?
BladeFLASK	146821	Independently tested by a NATA approved laboratory for compliance with AS 3825:2020 Standard “Procedures and devices for the removal and disposal of scalpel blades from scalpel handles”	Independently tested by a NATA approved laboratory for compliance with AS 4031-1992 Non-reusable containers for the collection of sharp medical items used in health care areas
BladeFlask EVO	146821	Independently tested by a NATA approved laboratory for compliance with AS 3825:2020 Standard “Procedures and devices for the removal and disposal of scalpel blades from scalpel handles”	Independently tested by a NATA approved laboratory for compliance with AS 4031-1992 Non-reusable containers for the collection of sharp medical items used in health care areas
BladeCASSETTE	134623	Independently tested by a NATA approved laboratory for compliance with AS 3825:2020 Standard “Procedures and devices for the removal and disposal of scalpel blades from scalpel handles”	n/a
BladeNeedleSYSTEM	208058	Independently tested by a NATA approved laboratory for compliance with AS 3825:2020 Standard “Procedures and devices for the removal and disposal of scalpel blades from scalpel handles”	n/a
BladeSINGLE	134623	Independently tested by a NATA approved laboratory for compliance with AS 3825:2020 Standard “Procedures and devices for the removal and disposal of scalpel blades from scalpel handles”	n/a
SnapIT	Not Applicable; not a medical device in Australia	n/a	n/a
CheckCLIP	134522	n/a	n/a

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