

GENERAL

| Product | Product Code | GMDN Code | Material | Latex | DEHP | Sterile | Method of sterilization | Re-usable | EAN Number | Packaging |
|-----------------|--|-----------|--|-------|------|---------|-------------------------|---|------------|---|
| BladeFLASK | QFYGEN | 46235 | Body: ABS (Acrylonitrile Butadiene Styrene) Inner mechanism: Polyacetal (POM), Stainless and Hardened Steel | No | No | No | – | Single-use sharps container; each unit removes up to 100 blades | Yes | Packaging have been successfully tested in accordance with the provisions of the United Nations Transport of Dangerous Goods, Chapter 6 |
| BladeFlask EVO | QBVYGEN | 46235 | Body: ABS (Acrylonitrile Butadiene Styrene) Inner Mechanism: ABS and Stainless Steel | No | No | No | – | Single-use sharps container; each unit removes up to 100 blades | Yes | Packaging have been successfully tested in accordance with the provisions of the United Nations Transport of Dangerous Goods, Chapter 6 |
| BladeCASSETTE | QSSVCAS-3Y /QSSVCAS-3R | 46236 | Polypropylene (PP) | No | No | Yes | Gamma | Single-use; each unit removes up to 3 blades | Yes | – |
| BladeNeedleSTEM | QBN202S | 46236 | Needle counter box: High Impact Polystyrene Cartridges: Polypropylene (PP) | No | No | Yes | Gamma | Single-use | Yes | – |
| BladeSINGLE | QSBS01 | 46236 | Polypropylene (PP) | No | No | Yes | Gamma | Single-use | Yes | – |
| SnapIT Personal | SN-01Rb (Blue) | 10098 | Aluminium | No | No | No | – | Multi-use | Yes | – |
| | SN-01Rp (Purple) | | | | | | | | | |
| SnapIT Trolley | TE-01R (Regular) | 10098 | Aluminium | No | No | No | – | Multi-use | Yes | – |
| | TE-01L (Large) | | | | | | | | | |
| | TE-01XL (Extra Large) | | | | | | | | | |
| SnapIT Lite | SN-02R (Regular) | 10098 | ABS (Acrylonitrile Butadiene Styrene) | No | No | No | – | Multi-use | Yes | – |
| | SN-02L (Large) | | | | | | | | | |
| CheckCLIP | For Vial: QSCCVIAL For Ampoule: QSCCGEN | 46240 | Polypropylene (PP) | No | No | No | – | Single-use | Yes | – |

UNITED STATES

| Product | General | FDA Classification Name | Device Class | 510(k) Number | Product Code | Regulation Number | Compliant Standard/s |
|-------------------|---|-------------------------|--------------|---------------|--------------|-------------------|--|
| BladeFLASK | Qlicksmart BladeFLASK is FDA 510(K) premarket approved (# K983367) as a sharps container. | container, sharps | II | K983367 | MMK | 880.557 | OSHA Bloodborne Pathogene Standard "1910.1030" |
| BladeFlask EVO | Qlicksmart BladeFlask EVO is FDA listed. | Blade, Scalpel | I | - | GES | 878.48 | OSHA Bloodborne Pathogene Standard "1910.1030" |
| BladeCASSETTE | Qlicksmart BladeCASSETTE is FDA listed. | Blade, Scapel | I | - | GES | 878.48 | OSHA Bloodborne Pathogene Standard "1910.1030" |
| BladeNeedleSYSTEM | Qlicksmart BladeNEEDLESYSTEM is FDA listed. | Blade, Scapel | I | - | GES | 878.48 | OSHA Bloodborne Pathogene Standard "1910.1030" |
| BladeSINGLE | Qlicksmart BladeSINGLE is FDA listed. | Blade, Scapel | I | - | GES | 878.48 | OSHA Bloodborne Pathogene Standard "1910.1030" |
| SnapIT | Qlicksmart SnapIT is FDA listed. | Surgical, General Use | I | - | MDM | 878.48 | - |
| CheckCLIP | Qlicksmart CheckCLIP is FDA listed. | Labelling | I | - | LYV | 878.48 | - |

UK/EU

| Product | Classification Rule | Measuring Function | Which MDD/AIMDD Annex(es) 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 | 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 | Yes | Donawa Lifescience , Piazza Albania 10, 00153 Rome, Italy, P.IVA o VAT Number 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 |
| BladeNeedleSTEM | 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 | - | - |

AUSTRALIA/NEW ZEALAND

| Product | TGA ARTG No | Compliant Standards for scalpel blade removal | Which Australian Standards for sharps containers have been used for conformity assessment? |
|-------------------|--|---|--|
| BladeFLASK | 146821 | AS 3825:2020 Procedures and devices for the removal and disposal of scalpel blades from scalpel handles | AS 4031-1992 Non-reusable containers for the collection of sharp medical items used in health care areas |
| BladeFlask EVO | 146821 | AS 3825:2020 Procedures and devices for the removal and disposal of scalpel blades from scalpel handles | AS 4031-1992 Non-reusable containers for the collection of sharp medical items used in health care areas |
| BladeCASSETTE | 134623 | AS 3825:2020 Procedures and devices for the removal and disposal of scalpel blades from scalpel handles | n/a |
| BladeNeedleSYSTEM | 208058 | AS 3825:2020 Procedures and devices for the removal and disposal of scalpel blades from scalpel handles | n/a |
| BladeSINGLE | 134623 | AS 3825:2020 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 |