

BladeFLASK and BladeFlask EVO

Compliance Summary

- ✓ **Meets AS 4031/92 Standard**
Meets or exceeds AS4031/92 requirements for sharps containers, specifically:
 1. Impact resistance
 2. Container stability
 3. Resistant to penetration
- ✓ **Meets AS 3825/2020 Standard**
Procedures and devices for the removal, containment and disposal of scalpel blades from scalpel handles.
- ✓ **ISO 23907-1:2019 Compliant**
Sharps injury protection - requirements and test methods – Part 1 single-use sharps containers
Tested and complies with the following:
 1. Resistant to penetration
 2. Drop test
 3. Container stability
 4. Unbreakable handle
 5. Topple and spill test
- ✓ **Certified with UN Transport requirements for dangerous goods.**
Testing meets or exceeds requirements of governmental and international organisations concerned with safety in the transport of dangerous goods for sharps containers.

- ✓ **ISO 13485:2016 (Medical Device) Compliant**
- ✓ **Australia - Listed under TGA ARTG NO: 146821.**

Complies with essential principles related to health and safety including long-term safety and risk-aversion.
- ✓ **USA - FDA 510(K) premarket approved #K983367 (BladeFLASK) and #K213274 (BladeFlask EVO) as a sharps container**

Device is safe and effective for use as a sharps container.
- ✓ **Europe - Class 1 medical device under (EU) MDR 2017/745, UK MDR 2002, and MedDO**

Device meets or exceeds the requirements to be legally marketed as a Class 1 (low risk) medical device.

