	<b>PRODUCT SAFETY DATA SHEET</b>	<b>Doc. No.:</b>	PSDS-01/03
	Surgical blades, Stitch cutters, Gouge Blades, Disposable Scalpels, Safety Scalpels, Thumb Scalpels. Podiatry Blade, Miniature & Fine Surgical Blades, Postmortem Blade, Grafting Blades	<b>Supersedes:</b>	PSDS-01/02
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## 1. Identification:

**1.1. Product Identification:** Surgical Blades, Stitch Cutters, Gouge Blades, Disposable Scalpels, Safety Scalpels, Thumb Scalpels, Podiatry Blades, Miniature & Fine Surgical Blades, Postmortem Blades, Grafting Blades.

**1.1.1. Product Type:** Sterile products are sterilized by Gamma irradiation. Gamma sterilization does not render the product radioactive.

**1.1.2. Brand Name:** KIATO, KIATO PLUS, APEXMED, CRISPIN, DIMEDA, HI CUT, HSO, PODOLINE, RUCK, SURGEON, YSIS, CARL MARTIN, MADIMEDIC, MEDIMEX, LAMDOR, PODOCUT, PODOMASTER, INSTRAPAC, and PETER.

## 1.2. Recommended Use and Restrictions:

**1.2.1. Recommended Use:** Surgical and medical cutting procedures by trained healthcare professionals only.

**1.2.2. Restrictions on Use:** Not intended for reuse unless specifically labeled reusable. Do not use non-medical applications.

**1.2.3.** e IFU is made available on the company website for detailed usage instructions.

## 1.3. Manufacturer Details:

**Name:** Aditya Dispomed Products Pvt. Ltd.

**Address:** Plot No 19, Sector 6, IMT Manesar Haryana 122050 India

**Telephone No.:** +91 124 4764914

**Email:** [info@adityadispomed.com](mailto:info@adityadispomed.com)

**Web:** [www.adityadispomed.com](http://www.adityadispomed.com)


## 2. Hazard Identification:

**2.1. Classification:** This product is a finished medical device/article and is not classified as a hazardous chemical under GHS.

## 2.2. Hazard Overview:

**2.2.1.** Sharp cutting edge may cause cuts or puncture injuries.

**2.2.2.** Used blades may present biological contamination risk after use.

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**2.3. Signal Word:** Warning

**2.4. Hazard Statement:**

**2.4.1.** May cause cuts and puncture wounds.

**2.4.2.** Used products may contain biohazardous contamination.

**2.5. Precautionary statements:**


**2.5.1.** Handle with care.

**2.5.2.** Use appropriate personal protective equipment.

**2.5.3.** Dispose of used blades in an approved sharps container.

### 3. Composition / Information on Ingredients:

S. No.	Component	Material	Alloy Designation / Specification / CAS No.
1.	Blade	Stainless Steel	ISO 7153-1:2016, "m", material number 1.4037 / X65Cr13. / ISO 10088-3:2023 EN 1.4037 / X65Cr13
		Carbon Steel	IS 7226:1974 Grade: 120Cr35
2.	Scalpel Handle	ABS	9003-56-9
3.	Cap	LLDPE	9002-88-4
4.	Safety Scalpel Handle	CYCOLOY - Polycarbonate / Poly (acrylonitrile-butadiene-styrene) Blend	9003-56-9
5.	Safety Cap	Polycarbonate	25037-45-0

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#### 4. First Aid Measures:

- 4.1. **Eye Contact:** Do not rub eyes. Gently flush eyes with clean water for several minutes if metal particles enter the eye keeping eyelid open. Cover with a sterile dressing and seek medical attention if irritation persists.
- 4.2. **Skin Contact:** For cuts or punctures, Apply firm direct pressure with a clean cloth to control bleeding. Do not attempt to remove an embedded blade and seek emergency medical care immediately if necessary.
- 4.3. **Inhalation:** Not applicable under normal use. If exposed to metal dust/fumes during processing, move to fresh air.
- 4.4. **Ingestion:** Not expected under normal conditions of use.
- 4.5. **Most Important Symptoms:** Cuts, puncture wounds, irritation from metal particles.

#### 5. Fire-Fighting Measures:

- 5.1. The finished product is not flammable under normal conditions of storage and use. Packaging materials may burn if exposed to fire.

#### 6. Accidental Release Measures:

- 6.1. **Personal Precautions:** Wear protective gloves while collecting blades. Avoid direct hand contact with sharp edges.


#### 7. Handling and Storage:

##### 7.1. Handling:

- 7.1.1. Handle carefully to avoid cuts.
- 7.1.2. Use only by trained personnel.
- 7.1.3. Avoid dropping or mishandling.

##### 7.2. Storage:

- 7.2.1. Store in a dry, clean area at the temperature conditions specified on the product packaging.
- 7.2.2. Protect from sunlight, moisture and corrosive environments.

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7.2.3. Keep in original packaging until use.

## 8. Exposure Controls / Personal Protection:

**8.1. Engineering Controls:** Not normally required for finished products.

### 8.2. Personal Protective Equipment:

**8.2.1.** Protective gloves


**8.3. Exposure Limits:** Not applicable for finished article under normal conditions of use.

## 9. Physical and Chemical Properties

Property	Value	
Physical State	Solid - metallic blade; with or without polymer handle depending on product variant	
Appearance	Blade	Metallic silver blade
	Scalpel Handle	Green
	Cap	Milky White
	Safety Cap	Transparent
Odor	Odorless	
pH	Not applicable	
Melting Point	Approx. 1370–1450°C	
Boiling Point	Not applicable	
Flash Point	Not applicable	
Flammability	Non-flammable	
Solubility	Insoluble in water	
Density	Approx. 7.5–8.0 g/cm <sup>3</sup>	

## 10. Stability and Reactivity:

**10.1. Stability:** Stable under recommended storage conditions. No decomposition is expected during normal use or storage within labelled shelf life.

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**10.2. Reactivity:** No specific reactivity hazards under normal conditions of handling, storage, or use. Stainless steel grades are corrosion-resistant under normal conditions. Carbon steel blade variants may corrode if exposed to moisture.

**10.3. Hazardous reaction:** No hazardous reactions under normal conditions.

**10.4. Conditions to avoid:** Excessive temperature & moisture (risk of packaging degradation and potential corrosion of carbon steel grades).

**10.5. Incompatible materials:** Strong oxidizing agents and acids.

**10.6. Hazardous Decomposition Products:** Under fire conditions or extreme thermal decomposition.

#### 11. Toxicological Information:

**11.1. Likely Routes of Exposure:** Skin contact, accidental puncture

**11.2. Acute Effects:** Cuts and puncture injuries

**11.3. Chronic Effects:** No known chronic health effects under normal intended use

**11.4. Carcinogenicity:** Not classified as carcinogenic in finished form

**12. Ecological Information:** No specific ecological hazards known for finished products.


**13. Disposal Considerations:** Dispose of used blades in approved sharps containers and according to local biomedical waste regulations.

**14. Transport Information:** Not regulated as dangerous goods for transport under normal shipping regulations.

#### 15. Regulatory Information:

**15.1.** Directive 2010/32/EU: Council Directive — prevention of sharps injuries in the hospital and healthcare sector

**15.2.** Standard 29 CFR 1910.1030: Applicable state medical waste regulations.

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**16. Disclaimer:** This PSDS summarizes our best knowledge of the health and safety hazard information of the product and how to safely handle and use the product in the workplace. Each user should read this PSDS and consider the information in the context of how the product will be handled and used in the workplace including in conjunction with other products. If clarification or further information is needed to ensure that an appropriate risk assessment can be made, the user should contact this company. Our responsibility for products sold is subject to our standard terms and conditions.