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Disposable Surgical Blade Manufacturing

1. Company Overview

With over 55 years of manufacturing expertise, Aditya Dispomed is a leading manufacturer of disposable surgical blades and scalpels supplying OEM customers, distributors and procedure kit manufacturers worldwide. Our products are used extensively in regulated healthcare markets where consistency, traceability and predictable performance are essential.

A significant portion of our production is supplied for use in sterile procedure kits, where product performance after sterilisation and over shelf life is a critical requirement.

2. Product Scope

The range of products offered by us covers:

- Safety scalpels (retractable sheath design) & Disposable Scalpel
- Surgical blades with and without RIB
- Special blades including stitch cutters and fine surgical blades

Products are supplied sterile or non-sterile, depending on customer requirements, and are intended for single use.

3. Manufacturing & Process Control Philosophy

Blade performance is achieved through controlled manufacturing processes, rather than reliance on end-of-line inspection alone. Key aspects of our manufacturing approach include.

- Controlled raw material selection suitable for medical cutting applications
- Defined process parameters at critical manufacturing stages
- In-process monitoring of key characteristics influencing blade performance

Final inspection and lot release under documented quality controls

This approach supports consistency across production lots and predictable performance in downstream use.

Our manufacturing capability was further strengthened in 2024 through the successful integration of the former B. Braun surgical blade manufacturing operation in Malaysia, significantly expanding production capacity, fine blade capability and manufacturing responsiveness.

4. Quality Management System

Manufacturing is conducted under an ISO 13485 certified Quality Management System.

Our quality system includes:

- Documented procedures and work instructions
- Lot traceability of manufactured products
- Non-conformance handling and corrective action
- Documented change control for materials, processes, and tooling

Quality documentation and technical information can be provided to support customer qualification and regulatory review, as required.

5. Sustainability, Environment & Occupational Safety

Aditya Dispomed is committed to responsible manufacturing practices that minimise environmental impact and promote safe and healthy working conditions. The organisation operates certified management systems in accordance with ISO 14001 (Environmental Management System) and ISO 45001 (Occupational Health and Safety Management System). These systems support systematic identification and control of environmental aspects, compliance with applicable legal requirements, continuous improvement in environmental performance, and proactive management of occupational health and safety risks.

6. Change Control & Customer Notification

Any change that may impact product material, manufacturing process, or performance characteristics is managed through documented change control procedures.

Where applicable, customers are informed in advance and provided with relevant technical information to support assessment and approval.

7 Sterilisation & Kit Experience

We have experience supplying blades used in sterilised medical products and procedure kits, including exposure to EO and Gamma sterilisation environments.

Manufacturing and material selection take into account the need for:

- Edge stability following sterilisation
- Resistance to corrosion or surface degradation
- Consistent performance throughout stated shelf life

8. Supply Capability & Reliability

Production planning is structured to support repeat orders and long-term supply relationships.

Key elements include:

- Typical manufacturing lead times of approximately **30 days** for standard products.
- Defined manufacturing capacity and lead times
- Skilled production personnel trained for blade manufacturing processes
- Redundancy in critical manufacturing operations
- Focus on continuity of supply and on-time delivery

9. Commercial & Relationship Approach

We work with customers on a long-term basis, supporting qualification processes, validation requirements, and volume scale-up over time.

We are accustomed to operating as an approved supplier within structured procurement and quality frameworks.

Closing Statement

Aditya Dispomed combines more than five decades of manufacturing expertise with continuous investment in advanced manufacturing technology, regulatory compliance and supply chain resilience. We are committed to building long-term partnerships with OEM customers and distributors by delivering premium product quality, dependable supply and responsive technical support.