Purchasing Control Policy

[Company Name], Inc.

Role	Position/Department	Name	Date
Author			DD YYYY
Reviewer			DD YYYY
Approver			DD YYYY

Revision History

Ver.	Details			
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	Role	**Author**	**Reviewer**	**Approver**
	Department	XXX	XXX	XXX
	Position	XXX	XXX	XXX
	Name	XXX	XXX	XXX

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Purpose

The purpose of this policy is to establish the criteria and requirements for the selection, evaluation, re-evaluation, and ongoing management of suppliers for all medical device products handled by [Company Name], Inc. (hereinafter referred to as “the Company”), ensuring the rational operation of purchasing activities and securing stable transactions in terms of quality, cost, delivery, and supply volume.

This policy conforms to the requirements of ISO 13485:2016, Clause 7.4 (Purchasing) and 21 CFR Part 820 — Quality Management System Regulation (QMSR).

Scope

This policy applies to all purchasing activities related to medical device products handled by the Company. This includes the procurement of components, materials, subassemblies, finished products, and services from external suppliers.

This policy applies a risk-based approach, where the type and extent of supplier controls are proportionate to the effect of the purchased product on subsequent product realization processes or on the final medical device.

Normative References

ISO 13485:2016 — Medical devices — Quality management systems — Requirements for regulatory purposes

21 CFR Part 820 — Quality Management System Regulation (QMSR)

ISO 14971:2019 — Medical devices — Application of risk management to medical devices

Definitions

Term	Definition
Quality Management System (QMS)	A formalized system that documents processes, procedures, and responsibilities for achieving quality policies and objectives. In this policy, QMS refers to the system established in accordance with ISO 13485:2016 and 21 CFR Part 820 (QMSR).
Supplier	An organization or person that provides a product or service. Suppliers include contract manufacturers, component vendors, service providers, and consultants. (ISO 13485:2016, Clause 3.16)
Outsourced Process	A process that the Company has identified as needed for its quality management system, but has chosen to have performed by an external party. (ISO 13485:2016, Clause 4.1.5)
Purchased Product	Components, materials, assemblies, products, or services procured from a supplier for use in or in support of the Company’s medical device products.
Purchasing Information	Information communicated to a supplier that specifies the conditions the supplier must meet for the purchased product, including specifications, drawings, manufacturing conditions, and quality requirements. Also referred to as purchasing requirements.
SCAR (Supplier Corrective Action Request)	A formal request issued to a supplier requiring investigation, root cause analysis, corrective action, and verification of effectiveness for a nonconformity attributable to the supplier.
Supplier Control Category	A classification (A, B, C, D, or S) assigned to a supplier based on the risk impact of the purchased product on the final medical device. The category determines the type and degree of supplier controls applied.
Approved Supplier List	A controlled list of suppliers that have been evaluated, approved, and