CONTROL OF NONCONFORMING PRODUCT

Standard Operating Procedure

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1. PURPOSE

This procedure defines the process for identifying, documenting, evaluating, and dispositioning nonconforming products, materials, and components. It ensures that nonconforming items are controlled and prevented from unintended use or delivery.

2. SCOPE

This procedure applies to all nonconformities identified in:

- Incoming materials and components
- In-process products and intermediates
- Finished products before release
- Products returned from customers
- Products identified during post-market activities

3. DEFINITIONS

Term	Definition
Nonconformity (NC)	Non-fulfillment of a specified requirement
Disposition	Decision on how to handle nonconforming product (rework, scrap, use-as-is, etc.)
Containment	Immediate action to prevent further use or distribution of NC product
Concession	Permission to use or release product that does not conform to specified requirements

5.2 RISK-BASED ASSESSMENT

Each nonconformity shall be assessed using the NC Assessment Matrix to determine:

Classification	Severity	Action Required
Critical	Patient safety impact	Immediate containment, mandatory CAPA
Major	Significant quality impact	Containment, CAPA evaluation required
Minor	Limited impact	Standard disposition, CAPA optional