

Medical Device Packaging Specification Document

1. Document Information

Document Number	
Revision	
Effective Date	
Prepared By	
Approved By	

2. Device Information

Device Name	
Catalog Number	
Description	

3. Packaging Configuration

- Primary Packaging:
- Secondary Packaging:
- Tertiary Packaging:

4. Materials and Components

Part	Description	Material	Supplier	Specification

5. Labeling Requirements

- Label content
- Placement
- Applicable standards

6. Packaging Process

- Cleaning/Sterilization (if applicable)
- Assembly instructions
- Sealing method
- Packaging diagram (if applicable)

7. Storage and Shipping Conditions

- Temperature range
- Humidity range
- Special Instructions

8. Acceptance Criteria

- Visual inspection
- Integrity testing
- Label verification

9. Change History

Rev	Date	Description	Prepared by
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