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## Packaging validation protocol

### 1. Scope of the Protocol

- Manufacturer Name
- Product Name & Description

### 2. International References

- Relevant Standards (ISO/ASTM)

### 3. Packaging System Description

- Packaging Specifications & Dimensions
- Sterile Barrier System Description
- Packaging Process Description
- Welding Parameters:
  - Machine Description
  - Welding Temperature & Time

### 4. Test Ambient Conditions

- Temperature & Relative Humidity

### 5. Packaging System Validation

- **Installation Qualification (IQ)**
- **Operational Qualification (OQ)**
- **Performance Qualification (PQ)** – Test Methods:
  - Visual Inspection
  - Dye Migration Test
  - Seal Peel Test
  - *Or equivalent tests based on product nature, referring to relevant standards*

### 6. Enclosures

- Packaging Samples
- Test Equipment Printouts
- Accreditation Certificate (for External Lab)