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ISO 11607 Compliance Whitepaper

Understanding the requirements of ISO 11607-1/-2 and EN 868-5 and how to implement them.

Scope of ISO 11607

ISO 11607 applies to industry, healthcare facilities and anyone packaging medical devices that are sterilized after packaging. It ensures the packaging system maintains sterility to the point of use and allows aseptic presentation.

Part 1 — materials and sterile barrier systems

Requirements: demonstrated microbial barrier, compatibility with the sterilization process, freedom from toxic substances, suitability for labelling, stability in storage, protection through distribution and demonstrable seal integrity.

Part 2 — validation of packaging processes

Installation, operational and performance qualification of forming and sealing equipment; definition of critical parameters (temperature, pressure, dwell time); routine monitoring. In a CSSD this means validating and monitoring the heat sealer.

Relationship to EN 868

EN 868-5 gives detailed requirements and test methods for paper/film pouches and reels and is used to demonstrate material conformity with ISO 11607-1.

Supplier documentation checklist

- Statement of conformity to ISO 11607-1 and EN 868-5 per product
- ISO 13485 certificate of the manufacturer
- Test data: microbial barrier, seal strength, burst, peel, indicator performance
- Lot traceability and shelf-life statement

Kangde Med provides this documentation for all pouches and reels on request.