

Summary - Packaging System Integrity for Sterile Medical Devices

The microbial barrier properties of the materials should be determined by comparing the extent of bacterial or particulate penetration through the material with the original challenge.

Critical factors that affect packaging system integrity for sterile medical devices include, and are not limited to:

- Packaging components composition, dimensions, coatings, and critical defects;
- Sealing/packaging operation variables of time, temperature, pressure (seal force), gas flow rates, torque limit, and energy level/frequency (radio frequency/ultrasonic);
- Processing variables of packaging components including washing, drying, siliconization, and sterilization; and
- Final product processing, such as terminal sterilization.

Sealing equipment commissioning and/or qualification should include and not be limited to:

- Verification that the sealing equipment is installed according to design criteria;
- Verification of mechanical operation (e.g., valves, hydraulic vacuum pumps, heating elements);
- Identification of utilities and instruments and elements (I/Es);
- Calibration of I/Es;
- Testing of alarm systems; and
- Verification that equipment operates properly throughout the Normal Operating Ranges.

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