Regulatory Basis:
FDA Quality Systems Regulations

Reference: FDA CFR - Code of Federal Regulations Title 21

General Discussion
This document provides guidance for determining the suitability of packaging materials and the evaluation and testing of the integrity of packaging systems for sterile Medical Devices manufactured and/or packaged by GMP sites.

1. The Suitability of a Packaging System should be confirmed by testing the quality attributes of the medical device over its shelf life.

2. Studies should be executed to simulate the effects of environmental stresses, handling, and use conditions on the packaging system including, and not limited to:
   - Temperature, pressure, and relative humidity extremes;
   - Shock and vibrational stress (e.g., shipping trials); and
   - Exposure to light.

3. The Microbial Barrier Properties of Impermeable Packaging Materials should be evaluated by using methods that demonstrate that the material is impermeable (e.g., dye penetration and Schopper method for determination of air permeability).

4. The Microbial Barrier Properties of Porous Packaging Materials should be evaluated by challenging samples with an aerosol of bacterial spores or particulates under a set of test conditions, which specify flow rate through the material, microbial challenge to the sample, and duration of tests. 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.

5. 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.

6. Quality Properties of the Final Packages produced at the both the upper and lower process parameter range limits should be considered for evaluation, including and not limited to:

   For forming/assembling:
   - Package completely formed/assembled,

