

Overview of SaniSure's Sterility Validation to Establish Two Year Shelf Life

May 19, 2019

Dear Valued Customer,

The purpose of this document is to provide an overview of SaniSure's Sterility Validation to Establish Two Year Shelf Life. The primary objective of the sterility validation was to be in full compliance with ISO 11137, which allows SaniSure to claim a sterility assurance level (SAL) of 10^{-6} for Single Use Systems over its shelf life of two years. The purpose of the study was to evaluate the effects of gamma irradiation and subsequent two year accelerated aging on the Single Use Systems Family with their associated packaging.

This study simulated the effects of real-time aging by subjecting the components to elevated temperatures according to the ASTM Standard F 1980 07, "Standard Guide for Accelerated Aging of Sterile Medical Device Packages".

The assumption in an accelerated aging test is that chemical reactions involved in deterioration of materials follows the Arrhenius function in that a 10°C increase in temperature results in approximately a 2-fold change in the deterioration reaction rate. In practice, storage at 55°C for 45.6 days will simulate one year of storage at 25°C . Standard F-1980 notes that 25°C is a conservative temperature choice for ambient storage comparison.

Prior to the accelerated aging process, the samples were gamma irradiated at the validated dose range of 27.5-45 kGy. Sterigenics is the sub-contractor used for the gamma irradiation and testing was done in conjunction with SteriPro Labs (Contract Laboratory).

Samples were processed at $55 \pm 2^{\circ}\text{C}$ and were retrieved at various time points to simulate shelf life of 0, 1 and 2 years. The processed samples were tested for dye migration, burst test and product sterility. This sterility hold was successfully validated. Products that are packaged at the SaniSure facility and gamma irradiated at the validated dose range of 27.5-45 kGy can be given a shelf life of two years and assurance of sterility within this shelf life time period. The shelf life of these products is dependent upon the storage conditions.

Shelf Life Statement: Single Use Systems Family Products

In general, it is best to store SaniSure assembly products in a cool dry environment (room temperature) shielded from direct sunlight. It is best to store in the manufacturer's original packaging until ready to use.

The shelf life of these products is two years from date of manufacture if the storage conditions comply with those described above.