



## Statement Regarding Storage, Shelf Life, and Shipping Conditions

The shelf life of SaniSure products is dependent upon the storage conditions. In general, it is best to store these products in a cool dry environment (ambient temperature, 20-25°C) shielded from direct sunlight. It is best to store in the original packaging until ready to use. Shipping conditions for SaniSure products should also be at ambient temperature as well.

The shelf life of gamma irradiated SaniSure products is two years from date of manufacture if the storage conditions comply with those described above. This shelf life period was validated at a dose range of 27.5-45 kGy. The primary objective of the 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.

Therefore, products that are packaged at the SaniSure facility and gamma irradiated at this validated dose range can be given a shelf life of two years and assurance of sterility within this shelf life time period.