Compliance and Processing Information for SaniSure PVDF Stir Bar Products

Processing
The preliminary fabrication steps for stir bars are performed by an ISO 9001:2015 certified machining service provider. The final fabrication, cleaning and packaging steps take place at SaniSure in controlled environments (ISO Class 7 cleanrooms and a controlled Fabrication environment).

Materials of Construction
The SaniSure Stir Bar products are manufactured from Kynar 700 series, PVDF (Polyvinylidene Fluoride resin) and a neodymium magnet, material is NdFEB, grade N42.

Country of Origin
All raw materials used in these stir bar products are sourced from United States based companies. All processing operations are performed in the United States as well.

Biocompatibility
This PVDF material meets Class VI (USP <88>) requirements and is in compliance with FDA 21 CFR 177.2510 regulations.

Sterilization
Non-sterilized stir bars are immediately shipped to the customer after the final inspection step. If the stir bars require sterilization they are shipped to the gamma irradiation service provider. They are irradiated at a dose range of 27.5-45kGy. Upon return to SaniSure, they are inspected one additional time and can then be shipped to the customer.
Kynar PVDF material is very resistant to gamma irradiation and can withstand dose levels in excess of the current dose range of 27.5-45kGy.

Statement Regarding Storage Conditions and Shelf Life (Sterile and Non-Sterile)
The shelf life of gamma irradiated SaniSure stir bar 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.

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

The shelf life of non-gamma irradiated stir bar products is indefinite as the degradation of the Kynar PVDF material over a long period of time is negligible. The recommended storage conditions stated above must also be followed.

Animal Derivative Content & Transmissible Spongiform Encephalitis (BSE/TSE) Risk
Based on information provided by our suppliers, the Kynar PVDF material used in these products is free of substances which are animal derived or associated with BSE/TSE infectivity.

Allergens
The materials used to manufacture these products do not contain allergens as defined by the FDA (Milk, Eggs, Fish, Crustaceans, Soy, Wheat, Latex, Gluten-containing sources, Peanuts and Tree Nuts) and do not come in contact with these allergens during the manufacturing or packaging process.

Conflict Minerals
Conflict minerals are not used in the formulation of the raw material or stir bar products.

Bisphenol A (BPA) and Phthalates
BPA and Phthalates are not used in the formulation of the raw material or manufacture of these SaniSure stir bar products.

Melamine
Melamine is not used in the formulation of the raw material or manufacture of these SaniSure stir bar products.

Genetically Modified Organisms (GMO)
The component materials used in the manufacture of these assemblies are synthetic in nature and produced by chemical synthesis. Genetically Modified Organisms are not used in the manufacturing or processing of any of the materials used in these assemblies that come in contact with the fluid pathway.

Restriction of Hazardous Substances (RoHS) - EU
Restrictions on the use of certain hazardous substances in electric and electronic equipment as defined in Directive 2011/65/EU and amendments in force (including Directive (EU) 2015/863) effective November 21, 2017. Based on a review of the final product composition by the resin manufacturer, there are no RoHS substances known to be present above the reporting threshold.

Substances of Very High Concern (SVHC)
This paragraph concerns substances listed in the Candidate List of Substances of Very High Concern, in accordance with Article 59 of the European Regulation 1907/2006 effective April 25, 2018. Based on a review of the final product composition by the resin manufacturer, this product is not a Substance of Very High Concern and does not contain any SVHC substance(s) above the declaration threshold.