

## **PLTS-R and PLTS-65 Platinum-Cured Silicone Tubing Regulatory Statement**

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### **Manufacturing Standard**

The above material is manufactured in an ISO 9001:2015 accredited facility. Furthermore, this product is manufactured in an ISO 14644-1 Class 7 cleanroom.

### **Dimensional Tolerances**

Inside and outside diameter tolerances are maintained to RMA E1 tolerances. Overall length tolerance is maintained to +6in. (min.) / -0 in.

### **Regulatory Testing**

- **Biocompatibility (USP 87 and USP 88)**

Based on the testing performed by SaniSure on representative samples of the above product, this product meets the requirements of the standards listed below:

- USP 87\*
- USP 88\*

- **Biocompatibility (ISO 10993 and USP Class VI)\***

A Representative sample of the compound used to manufacture this product has been tested according to ISO 10993 and USP Class VI testing requirements. The sample met the requirements of the following tests:

- Systemic Injection Test (USP Class VI and ISO 10993)
- Intracutaneous Toxicity Test (USP Class VI and ISO 10993)
- Intramuscular Implantation Test (USP Class VI and ISO 10993)
- Agar Diffusion (ISO 10993-5)
- L929 MEM Elution (ISO 10993-5)
- Implant Effects (ISO 10993-6)
- Sensitization (Kligman Maximization) (ISO 10993-10)
- Systemic Toxicity (ISO 10993-11)

- **Extractables - USP**

Based on the testing performed by SaniSure on representative samples of the above product, this product meets the requirements of the standards listed below:

- USP 665\*
- USP 661.2\*

- **Extractables - FDA Food Contact\***

Based on the testing performed by SaniSure on representative samples of the above product, this product meets the requirements of the standards listed below:

- FDA 21 CFR 177.2600

- **Endotoxin Testing**

Based on the testing performed by SaniSure on representative samples of the above product, this product meets the requirements of the standards listed below:

- USP 85 - LAL Bacterial Endotoxin Testing\*

- **Particulate Testing**

Based on the testing performed by SaniSure on representative samples of the above product, this product meets the requirements of the standards listed below:

- USP 788\*

\*The assessment is available upon request at <https://sanisure.com/get-report/>

## **Presence of Substances**

Based on the information provided to SaniSure by its raw material suppliers and our formulation reviews, we have found that the product listed does not intentionally contain the following substances:

- Bisphenol A (BPA)
- Melamine
- Latex
- N-Nitrosamines
- Phthalates
- Polyvinyl chloride (PVC)
- Slip Agents

## **Regulatory Compliances**

Based on the information made available to us by our raw material supplier, the above material is compliant to the below list of regulatory requirements.

- RoHS Compliant
- REACH Compliant (224 SVHC)
- Conflict Minerals
- California Proposition 65
- ICH Q3D Guideline for elemental impurities

## **Animal Derivatives, Plant Derivatives, BSE/TSE Statement\***

Based on the information provided to SaniSure by its material suppliers and review of our product formula and our materials handling and processing procedures, we have been able to determine that the product listed above does not contain ingredients derived from animals including animal fats (tallow). Based upon this information there would be no known sources of Bovine Spongiform Encephalopathy (BSE) or Transmissible spongiform encephalopathy (TSE).

### **Genetically Modified Organisms (GMO)**

This product is not manufactured with any genetically modified organisms (GMO's).

\*Please note that the information provided is based on best available knowledge; we do not test for the presence of trace amounts of substances that may be introduced our products as contaminants. We do not routinely analyze our products for the presence of the above reportable substances; however, based on information provided by our supplier and to the best of our knowledge, the above material is free from animal derivatives.

## **Allergens**

Based on the information provided to SaniSure by its supplier and our documentation reviews, we have found that the product listed above does not intentionally contain any of the below allergens

- Gluten
- Lactose
- Nuts
- Egg/Protein
- Soy
- Nickel
- Zinc
- Fish/Shellfish

## **Sterilization**

### **Gamma Irradiation**

The recommended maximum dosage for gamma irradiation of the above product is 50kGy. When required of SaniSure, the standard range for gamma irradiation of products is between 25 and 40 kGy.

### **Autoclave**

Autoclaving at cycles of 10 minutes @ 130C and 30 psi or 30 minutes @ 121C and 15 psi can be carried out. If repeated autoclaving is to take place, then the user must be satisfied as to the usability of the tubing following each cycle. Care must be taken that all autoclave procedures are carried out under the correct conditions of temperature and pressure.

## **Shelf Life and Storage Conditions**

If stored according to the following recommendations, SaniSure recommends that customers dispose of this product after eight (8) years from the date of manufacturing. Store this product in a dry inside environment with a target ambient temperature of 77°F and humidity of less than 65%. The product should be free from exposure to direct outside weather influences and stored in a dark space out of direct contact with light. The area should be free from volatile solvents, corrosive gases, or other potentially harmful vapors. Stack the product flat in an opaque container during storage. The container should be kept off the floor (e.g., on shelving or skids) and remain closed and sealed while in storage. The product should be free of kinking and not be subjected to crushing forces from the weight of the product above it.

SaniSure makes no representations or warranties as to the accuracy of the information contained or referenced herein.–Most results mentioned above are based on single lots of material. Although a lot-to-lot variance would not be expected to show different results, this data should not be construed as a warranty of fitness for use. Prior to use for any application, the user has the sole responsibility for determining the suitability of these products in any application. If you have any questions concerning this document or if we can be of further assistance, please do not hesitate to contact us. Please do not hesitate to contact our quality department at [quality.nj@sanisure.com](mailto:quality.nj@sanisure.com) or 973.383.2834 for more information.

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