

Re: FEP Tubing Regulatory Statement

21CFR177.1550

Based on the information made available to us by our material provider, the above product meets the requirements of 21CFR177.1550

Animal Derived Ingredient Free

Based on the information made available to us by our material provider, the above product is not expected to contain animal derived ingredients.

Latex

Based on the information made available to us by our material provider, the above product is not expected to contain latex.

REACH

Based on the information made available to us by our material supplier, this finished product is made from a material which does not emit or release chemicals under normal circumstances and are therefore exempt from REACH registration.

RoHS

Based on the information made available to us by our material provider, the above product does not intentionally contain any materials restricted by RoHS above the reporting threshold.

Shelf Life and Storage

Based on the information made available to us by our material provider, the above product has a near-indefinite shelf life when stored properly. Storage conditions are ambient temperature, in the product's original package, and away from direct sunlight.

USP Class VI

Based on the information made available to us by our material provider, the above product meets the requirements of USP Class VI.

The information submitted is valid as of the date of this letter. TBL makes no representations or warranties as to the accuracy of the information contained or referenced herein as of any other date. 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 or 973.383.2834 for more information.

Respectfully,

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