

Product Certificate

July 9, 2020

The following information represents Product Certification for:

Catalog Number: **343050-0005**
Lot Number: **7338307010**
Description: **Tank Liner, 19L / 5 Gal, 25kGy**
Date of Manufacture: **03/26/2020**

Material Information:

Description	Cytotoxicity	USP Class VI	FDA Compliance
Liner Material – 5.0 mil LDPE & LLDPE	Passed	Passed	21 CFR 177.1520(c)3.2a, 174.5, 176.170(c) Use conditions A-H

If the word “Passed” appears in the USP Class VI column, this material has passed USP Class VI requirements, latest volume, as part of our initial test approval protocol.

If the word “Passed” appears in the Cytotoxicity column, this material was tested and shown to be non-cytotoxic as part of our initial test approval protocol, using either mouse fibroblast L929 cells or the more sensitive human diploid lung cell lines WI-38 or MRC-5.

Product was Gamma Irradiated between 25 – 40 kGy.

Product was determined to be non-pyrogenic at a level < 0.5 EU/ml per USP <85>.

Thermo Fisher Scientific hereby certifies that the product identified below is inspected and released according to the requirements of product and quality specifications as maintained in our quality management system which is compliant to ISO 13485:2016 (BSI Certificate Number: FM 653694).

Sincerely,

Tammy Parmelee

Tammy Parmelee
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