

Certificate #21024



Certificate of Compliance

for



PharmaTainer™ PET Container with PharmaTainer™ HDPE Cap After Gamma Irradiation

The BioProcess Institute certifies that SaniSure®'s
PharmaTainer™ PET Container with PharmaTainer™ HDPE Cap After Gamma Irradiation
is biocompatible and meets USP and ISO Standards:

- *U.S. Pharmacopeia 43, National Formulary 38 (USP), General Chapter <87>, Biological Reactivity Tests, In Vitro (2020)*
- *U.S. Pharmacopeia 43, National Formulary 38 (USP), General Chapter <88> Class VI, Biological Reactivity Tests, In Vivo (2020)**
- *ISO 10993-5 – Part 5: Tests for in vitro Cytotoxicity (2009)*
- *ISO 10993-6 – Part 6: Tests for Local Effects after Implantation (2016)*
- *ISO 10993-10 – Part 10: Tests for Irritation and Skin Sensitization (2010)*
- *ISO 10993-11 – Part 11: Tests for Systemic Toxicity (2017)*

**The PharmaTainer™ PET Container with PharmaTainer™ HDPE Cap was gamma irradiated to 50 kGy, prepared as a fill device, and extracted at 50°C for 72 hours.*

The test reports associated with these studies are summarized in
The BioProcess Institute's August 10, 2021 Final Report for Project #2037.
Additional COC References: 21026, 21031.

James Dean Vogel, P.E.
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THE BIOPROCESS INSTITUTE

19 August 2021

Date