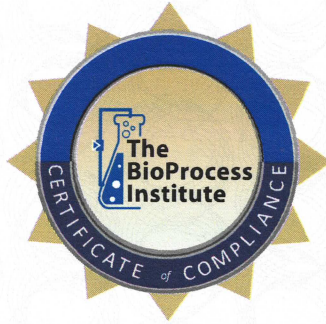


Certificate #21025



# Certificate of Compliance

for



## PharmaTainer™ PC Container with PharmaTainer™ HDPE Cap After Gamma Irradiation

The BioProcess Institute certifies that SaniSure®'s  
**PharmaTainer™ PC 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™ PC 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, 21032.

James Dean Vogel, P.E.  
Founder & Managing Director  
THE BIOPROCESS INSTITUTE

Date