

World Leader in Testing Services for the Medical Device Industry

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Attn: DR. WALTER BRENNER

LAB NO. 91T-09580-00 P.O. NO. 06021091

ID NO. Not Supplied

CERTIFICATE OF COMPLIANCE

USP BIOLOGICAL TESTS CLASSIFICATION VI

Test Article: Epoxy System EP21LV

ACUTE SYSTEMIC TOXICITY (USP): The saline, alcohol in saline, polyethylene glycol 400 and cottonseed oil extracts of the test article injected into mice did not produce a significantly greater systemic reaction than the blank extractant.

INTRACUTANEOUS TOXICITY (USP): The saline, alcohol in saline, polyethylene glycol 400 and cottonseed oil extracts of the test article injected intracutaneously in rabbits did not produce a significantly greater tissue reaction than the blank extractant.

<u>IMPLANTATION TEST (USP)</u>: The macroscopic reaction of the test article implanted 7 days was not significant as compared to the USP Negative control plastic.

The sample of test article extracted at a ratio of 60sq.cm/20 m1 and at a temperature of 50°C for 72 hour(s) met the requirements of a USP Class VI Plastic.