

**CERTIFICATE  
OF COMPLIANCE  
USP BIOLOGICAL TESTS  
CLASSIFICATION VI**

**Material:** **SILPURAN® 6000/50, WE 08930**

**Manufacturer:** WACKER Chemic AG, Germany  
WACKER Chemical Corporation, USA  
WACKER Asahikasei Silicone Co. Ltd., Japan

**Studies performed:**

**ACUTE SYSTEMIC TOXICITY (USP)**

The saline, alcohol in saline, polyethylene glycol 400 and vegetable oil extracts of the test item 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 vegetable oil extracts of the test item injected intracutaneously in rabbits did not produce a significantly greater tissue reaction than the blank extractant.

**IMPLANTATION TEST (USP)**

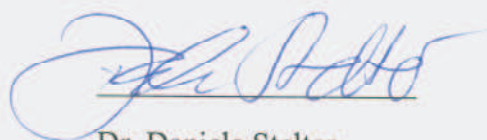
The macroscopic reaction of the test item was not significant as compared to the USP negative control plastic after one weeks implantation.

The sample of the test item extracted at a ratio of 60 cm<sup>2</sup>/20mL and at a temperature of 121 ± 2°C for 1 hour met the requirements of a USP Class VI Plastic.

Suitable for use in manufacturing of medical devices for short term (no longer than 30 days) implant applications in accordance with the Wacker Health Care Letter and Guidelines.

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Biological Safety Testing



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