

CERTIFICATE OF COMPLIANCE USP BIOLOGICAL TESTS CLASSIFICATION VI

Material tested: Elastosil[®] LR3003/30 A,B Control No: SL15278

Manufacturer: WACKER Chemie GmbH, Germany
WACKER Silicones Corporation, USA
WACKER Chemicals East Asia 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 implanted 120 hours was not significant as compared to the USP negative control plastic.

The sample of the test item extracted at a ratio of 60 cm²/20ml and at a temperature of 50 ± 1°C for 72 hours 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.

BIOSERVICE Scientific Laboratories GmbH Munich

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A handwritten signature in blue ink, appearing to read "Albrecht Poth".

Dr. Albrecht Poth

Manager Biological Safety Testing

Date: December 28, 1998