CERTIFICATE
OF COMPLIANCE
USP BIOLOGICAL TESTS
CLASSIFICATION VI

Material tested: **ELASTOSIL® R4001/40 MH, Batch No: HM 26499**

Manufacturer: WACKER Chemie GmbH, Germany
WACKER Silicones 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 extract.

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 extract.

IMPLANTATION TEST (USP)

The macroscopic reaction of the test item implanted not less than 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 121 ± 1°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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