

BIOCOMPATIBILITY CERTIFICATE

Testmaterial: **Elastosil® R401/40 Control No: 33932HO**

Manufacturer: WACKER Chemie GmbH, Germany
WACKER Silicones Corporation, USA
WACKER Chemicals East Asia Ltd., Japan

Studies performed: The following studies were performed in order to determine the biocompatibility of the test item according to ISO 10993-1:

CYTOTOXICITY
HEMOLYSIS
PYROGENICITY
SENSITISATION
DERMAL IRRITATION
IMPLANTATION (90 days)

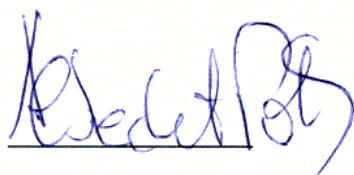
Results: **The test item showed no relevant biological effects in the studies performed.**

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.

BSL BIOSERVICE Scientific Laboratories GmbH Munich

Behringstraße 6

D-82152 Planegg



Dr. Albrecht Poth

Manager Biological Safety Testing



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