

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. Res

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

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BSL

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Dr. Albrecht Poth

afety Testing

Date: December 28, 1998

Manager Biological S