

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.

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Date: December 28, 1998