

# 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)**

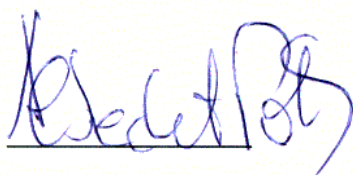
**Results:**                **The test item showed no relevant biological effects in the studies performed.**

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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