

BIOCOMPATIBILITY CERTIFICATE

Material tested: ELASTOSIL® R 401/30; Batch No: HN 11287

Manufacturer: WACKER Chemie GmbH, Werk Burghausen
Johannes-Hess-Str. 24, D-84489 Burghausen

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

CYTOTOXICITY

HEMOLYSIS

THROMBOGENICITY

PYROGENICITY

SENSITISATION

DERMAL IRRITATION

IMPLANTATION (90 days)

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

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Biological Safety Testing

Date: February 10, 2005

