

BIOCOMPATIBILITY CERTIFICATE

Testmaterial: Elastosil® LR3003/20 A,B Control No: 1823SL

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)

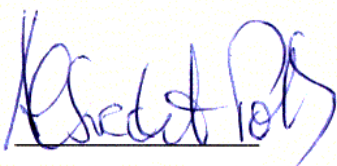
Results: The test item showed no relevant biological effects in the studies performed.

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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