TOXiKON
Leaders in Life Science and Technology

Henkel Corporation
1001 Trout Brook Crossing
Rocky Hill, CT 06067

Date of Test Completion: February 27, 2008
Project Numbers: 07-5478

Certificate of Compliance
ISO 10993 Biological Tests

Test Article: LOCTITE® 3590™ Resinaid™ Medical Device Molding Compound

Lot No: L37C000051

CYTOTOXICITY (ISO): The purpose of the MEM Elution is to determine biological reactivity of monolayer cell culture (L929) in response to the test article. The test article is considered non-cytotoxic and meets the requirements of the MEM Elution Test, ISO 10993-5.
Reference: Biological Evaluation of Medical Devices-Part 5: Tests for In Vitro Cytotoxicty Methods, ISO 10993-5, 1999.

BUEHLER SENSITIZATION (ISO): The purpose of the Buehler sensitization test is to evaluate the potential for sensitization of skin of guinea pigs following a topical application of the test article. The test article is considered a non-sensitizer and meets the requirements of the Buehler Sensitization Test, ISO 10993-10.
Reference: Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and Delayed-type Hypersensitivity, ISO 10993-10, 2002, as amended 2006.

PRIMARY SKIN IRRITATION (ISO): The purpose of the primary skin irritation is to assess the potential for dermal irritation after repeated topical exposure to the skin of New Zealand White Rabbits. The article is considered a negligible irritant and meets the requirements of the Primary Skin Irritant Test, ISO 10993-10.
Reference: Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and Delayed-type Hypersensitivity, ISO 10993-10, 2002, as amended 2006.

These studies are in conformance to all applicable laws and regulations. Specific regulatory requirements include the current Good Laboratory Practice for Nonclinical Studies (GLP), FDA, 21 CFR, Part 58.

Director of Biocompatibility

Quality Assurance

Date of Certificate: June 13, 2008

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