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Henkel Corporation
1001 Trout Brook Crossing
Rocky Hill, CT 06067

Date of Test Completion: August 24, 2007

Project Numbers: 07-2940

**Certificate of Compliance
ISO 10993 Biological Tests**

Test Article: Loctite® 3672™ Resinaid™ Medical Device Molding Compound

Lot No: L37D009065

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 extract is considered non-cytotoxic, at dilutions of 1:2, 1:4, and 1:8, and meets the requirements of the MEM Elution Test, ISO 10993-5.

Reference: Biological Evaluation of Medical Devices-Part 5: Tests for In Vitro Cytotoxicity Methods, ISO 10993-5, 1999.


BUEHLER SENSITIZATION (ISO): The purpose of the Buehler sensitization test is to assess the potential for sensitization of skin of guinea pigs following an induction phase and a challenge phase of exposure to the test article. The test article is considered a non-sensitizer and meets the requirements of the Buehler Sensitization Test, ISO 10993-10.

Reference: ISO 10993-10, 2002, Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Delayed-Type Hypersensitivity, as amended 2006.


PRIMARY SKIN IRRITATION (ISO): The purpose of the primary skin irritation is to assess the potential for skin irritation in rabbits following a dermal exposure of the test article. The article is considered a non-irritant and meets the requirements of the Primary Skin Irritant Test, ISO 10993-10.

Reference: ISO 10993-10, 2002, Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Delayed-Type Hypersensitivity, 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: September 21, 2007

Toxikon Corporation

15 Wiggins Avenue ▪ Bedford, Massachusetts 01730

800.458.4141 ▪ Main 781.275.3330 ▪ Fax 781.271.1136

► www.toxikon.com