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Loctite Corporation
Loctite Hearing Aid Products
1001 Trout Brook Crossing
Rocky Hill, CT 06067

Date of Test Completion: 10/27/04
Project Numbers: 04-3840

Certificate of Compliance ISO 10993 Biological Tests

Test Article: LOCTITE Resinaid™ 3590 Medical Device Molding Compound

Lot No: 4C363

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 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: Biological Evaluation of Medical Devices-Part 10: Tests for Irritation and Delayed-type Hypersensitivity:ISO 10993-10, 2002.


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 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.

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.

Cured Film Cure Conditions: Five (5) minutes per side, Zeta 7400 30 milliwatts/cm² @ 365 nm. Wipe the film with IPA (Isopropyl Alcohol) after curing. Approximate film thickness 1/2 mm.


Study Director


Quality Assurance

Date of Certificate: 10/29/04

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