

Project Number: 02-4426

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Certificate of Compliance
EN/ISO 10993 Biological Tests
[INCLUSIVE OF ADDITIONAL USP PHYSICOCHEMICAL TESTING]

HEMOCOMPATIBILITY (ISO):

Hemolysis: This assay is designed to evaluate the hemolytic potential of the test article extracts. Hemolytic activity of the test article with rabbit blood indicated that the test article was non-hemolytic (<5%).

Reference: Biological Evaluation of Medical Devices - Part 4: Selection of Tests for Interactions with Blood, ISO 10993-4, 1992.

In Vitro Hemocompatibility Assay: This assay is designed to ensure that the test material extract does not adversely affect the cellular components of blood. The test article was evaluated for its potential to adversely affect selected hematological parameters. The hematological parameters tested were complete blood count including platelets, hematocrit, erythrocyte indices and free plasma hemoglobin. The test article meets the requirements.

Reference: Biological Evaluation of Medical Devices - Part 4: Selection of Tests for Interactions with Blood, ISO 10993-4:1992.

IMPLANTATION TEST (ISO): The macroscopic and histological reaction of the test article, implanted in rabbit muscle for 2 weeks was not significant when compared to negative control sites-conforms.

Reference: Biological Evaluation of Medical Devices - Part 6: Tests for Local Effects After Implantation, ISO 10993-6: 1994.

PHYSICOCHEMICAL TEST (USP): This test determines the physical and chemical properties of extracts of test material. The test article passes the USP Physicochemical Tests for plastics.

Reference: United States Pharmacopeia 25, National Formulary 20, 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.

The adhesive bonded polycarbonate lap shears utilized to approximate typical medical device applications are disassembled prior to testing in order to maximize adhesive exposure during the respective tests. All test results reflect maximum exposure of the adhesive to the various test parameters and conditions. In this manner, the adhesive test results provide a higher margin of safety when compared to the tests involving only the bondline area and thickness.


Study Director


Quality Assurance

Date of Certificate: January 30, 2003