Summary

The test article, TT Fabric from Nan Ya, was evaluated for primary skin irritation in accordance with the guidelines of ISO I0993-10, Biological evaluation of medical devices - Pait I0: Tests for irritation and skin sensitization. Two 25 mm x 25 mm sections of the test article and control article were topically applied to the skin of each of three rabbits and left in place for 24 hours. The sites were graded for erythema and edema at I, 24, 48 and 72 hours after removal of the single sample application.

There was no erythema and no edema observed on the skin of the animals treated with the test article. The Primary Irritation Index for the test article was calculated to be 0.0. The response of the test article was categorized as negligible.

Supervisory Personnel:

Lisa A. Severhof, BA
Manager, Toxicology

Colleen M. Stevenson, AA
Supervisor, Toxicology

Study Director Approval:

Leah Irwin

Leah K. Irwin, BS
Medical Research Manager

5-31-13

Date Completed

Autho,ization for duplication of this report, except in whole, is reserved pending NAMSA's written approval.