

From: TIDI Products

Purpose:

Provide biocompatibility confirmation for medical and dental drapes and covers and securement devices (Grip-Lok) manufactured by TIDI Products.

Scope:

Medical and dental drapes and covers manufactured by TIDI Products:

- Handheld barriers – X-ray sheaths, Intra-Oral Camera Covers, and Curing Light Sleeves
- Medical equipment barriers – Many products both TIDI branded and private labeled.

Securement devices (Grip-Lok) manufactured by TIDI Products – Many products both TIDI branded and private labeled.

Summary

The material of construction used in the above product lines have met biocompatibility requirements for cytotoxicity, irritation, and sensitization per ISO 10993-1.

- Cytotoxicity per ISO 10993-5
- Irritation per ISO 10993-10
- Sensitization per ISO 10993-10

Results are documented in TIDI document documentation.

Thea Goodman

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