



December 21, 2006

To Whom It May Concern:

The following information is in response to a request for general and safety compliance information of our camera covers and sheaths to applicable standards.

- 1.) All of our probe cover products (i.e. thermometer sheath, instrument sheaths, and dental camera covers) are manufactured to the ASTM E1104-98 standard.
- 2.) The material construction is a combination of ethylene methyl acrylate copolymer (EMAC) and low density polyethylene (LDPE). Our materials do meet the requirements set forth by the FDA for poly products, as referenced in Part 177 of 21 CFR (specifically 177.1340 and 177.1520).
- 3.) There is no prescribed shelf-life period for our probe cover products. The products are provided non-sterile, and there have been no tests performed to determine a defined life of the materials used for construction. General, normal environmental conditions and practices for storage are acceptable.
- 4.) Our supplier of the EMAC has certified their materials to be in compliance with the following USP biological tests;
  - a. Acute systemic toxicity
  - b. Intracutaneous toxicity
  - c. Implantation testing
- 5.) Melting point data for the materials is as follow:
  - a. EMAC-softening point of 61C, melting point 82C. (The actual temperature could be slightly higher due to a % LDPE that is blended.)
  - b. LDPE – softening point of 96C, melting point of 115C.
- 6.) The materials used to manufacture these products do not contain natural rubber latex. This includes the packaging and any associated components to the product.
- 7.) Our probe cover products have undergone the following biocompatibility tests to the ISO 10993-1 standard;
  - a. Cytotoxicity
  - b. Skin Irritation
  - c. Skin Sensitization

- 8.) In addition, the combined EMAC and LDPE film used in the manufacturing of the probe cover products has passed viral penetration testing to the STM F 1671 standard.
- 9.) Our thermometer sheath products are listed with the FDA under 510(k) number K983406, device listing number B045589. These products are FDA classification II.
- 10.) Our camera cover/instrument sheath products fall under the FDA device listing number E185873. These products are FDA classification I, exempt from pre-market notification requirements.
- 11.) Our TIDI brand probe cover products are CE marked for distribution within the European Union.

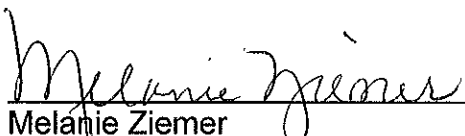
In addition, please note that TIDI Products, LLC is listed with the FDA (establishment number 2182318) and our quality system is certified in compliance with ISO 9001:2000 and ISO 13485:2000.

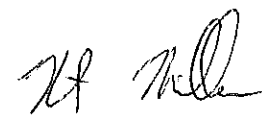
We truly hope this information helps your endeavors. If you have any further questions, please feel free to contact us:

TIDI Products, LLC    phone: 800-521-1314 x4352    fax: 800-837-7770    [www.tidiproducts.com](http://www.tidiproducts.com)

Sincerely,

TIDI Products, LLC  
Regulatory Team

  
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Engineering