



SEP 11 2000

Food and Drug Administration
Center for Devices and
Radiological Health
2098 Gaither Road
Rockville, MD 20850

VIA FEDERAL EXPRESS

WARNING LETTER

Mr. Rolf B. Schetz
Managing Director/CEO
Vis Extrusion, GmbH
Freiburger Strasse 23
D-77652 Offenburg, Germany

Dear Mr. Schetz:

During an inspection of your firm located in Offenburg, Germany on July 25, 2000, our investigator determined that your firm manufactures non-sterile suture materials. These are devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above-stated inspection revealed that these devices are adulterated within the meaning of section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Good Manufacturing Practice (GMP) for Medical Devices Regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820, as follows:

1. Failure to establish policy and objectives for, and commitment to quality ensuring that the quality policy is understood, implemented, and maintained at all levels of the organization, as required by 21 CFR 820.20(a). For example, no quality policy and objectives have been established and implemented.
2. Failure to establish procedures for quality audits and conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality system, as required by 21 CFR 820.22. For example, there are no audit procedures, and no audits have been conducted. The manufacturer stated it relies on customer audits to determine the adequacy of the system.
3. Failure to establish and maintain procedures for implementing corrective and preventive action including requirements for analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems, as required by 21 CFR 820.100(a)(1). For example, there are no

established approved procedures for implementing corrective and preventive actions.

4. Failure to establish and maintain procedures to control all documents that are required by this part providing for the designation of an individual(s) to review for adequacy and approve prior to issuance all documents established to meet the requirements of this part, as required by 21 CFR 820.40(a). For example, there are no procedures for document control.
5. Failure to review and approve changes to documents by an individual(s) in the same function or organization that performed the original review and approval, unless specifically designated otherwise, communicating the approved changes to the appropriate personnel in a timely manner, as required by 21 CFR 820.40(b). For example, there is no review or approval process for engineering changes.
6. Failure to establish and maintain calibration procedures to ensure that equipment is routinely calibrated, inspected, checked, and maintained, including provisions for handling, preservation, and storage of equipment, so that its accuracy and fitness for use are maintained, as required by 21 CFR 820.72(a). For example, there are no calibration procedures.

This letter is not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations.

The specific violations noted in this letter and in the form FDA 483 issued at the closeout of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the Food and Drug Administration. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts.

Please notify this office in writing within 30 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective actions cannot be completed within 30 working days, state the reason for the delay

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and the time within which the corrections will be completed. To date we have not received a response to the FDA 483 from you.

Your response should be sent to the Food and Drug Administration, Center for Devices and Radiological Health, Office of Compliance, Division of Enforcement I, General Surgery Devices Branch, 2098 Gaither Road, Rockville, Maryland 20850, to the attention of Carol Shirk.

Should you have questions or need further assistance, contact Carol Shirk at (301) 594-4595 or FAX (301) 594-4636.

Sincerely yours,



Larry D. Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health

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