



DEPARTMENT OF HEALTH & HUMAN SERVICES

ชำระค่าธรรมเนียมแล้ว
FEE PAID

Public Health Service

Royal Thai Embassy 01 SEP 2009

MAR 21 2002

Mr. Muhammad Saghir
Chief Executive Officer
Gobble Surgical
P.O. Gohad Pur
Sialkot, Pakistan

Islamabad, Pakistan

Certified genuine signature of

RAJA M. SARWAR KHAN

(Mr. Pramote Pramonsab)
Second Secretary/Consul

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

and

Mr. Javed Gill
Chief Executive
Proline Consulting
16/5 Church Road
Sialkot, Pakistan

ATTESTED

131 AUG 2009

Dear Messrs. Saghir and Gill:

Raja M. Sarwar Khan
Asst. Director
for Consular Affairs
Islamabad

This is to acknowledge receipt of a January 21, 2002, letter from Mr. Javed Gill certifying the compliance of Gobble Surgical (Gobble) with the Food and Drug Administration (FDA) Quality System Regulation of 1997, which includes the current good manufacturing practice (CGMP) requirements. The Quality System Regulation is set forth in Title 21, Code of Federal Regulations (CFR), Part 820. This also acknowledges a March 5, 2002, FAX from Mr. Gill responding to my February 11, 2002, email requesting further information. The consultant certification confirmed that a quality system audit of Gobble was performed January 8, 2002, and a corrective action plan was implemented and verified on January 18, 2002.

The quality system audit report states that Gobble manufactures reusable and single use surgical and dental instruments. Based on our review of the audit results and certification, Gobble has been placed on Attachment A of Import Alert #76-01. You may begin exporting devices to the United States (U.S.) that were manufactured after the consultant certified your firm's compliance with the CGMP's; however, your shipments may be subject to the guidance outlined in Attachment A of Import Alert #76-01. After five consecutive shipments comply with the import alert guidance, you may request your firm be placed on Attachment B. Submit your request directly to the FDA district office for their concurrence and further submission to this office for action.

The placement of the firm on Attachment A is limited to devices manufactured under the name of Gobble Surgical, P.O. Gohad Pur, Sialkot, Pakistan. In the event the manufacturing name and/or address change, FDA requests that notification be immediately forwarded to this office.



Page 2 - Messrs. Saghil and Gill

A change in the name and/or address of the manufacturing facility without notifying FDA will result in a re-evaluation of the compliance status of your firm.

The decision based on your consultant certification will remain in effect until such time as FDA is able to visit Sialkot, Pakistan for an inspection of your facility. During this inspection all corrections and procedures will be evaluated and confirmed. Any new CGMP deviations, or any uncorrected deviations that were previously certified to, may result in a re-evaluation of the compliance status of your firm, Gobble, including the possibility of removal from Attachment A.

We request that a quality system follow up audit be performed at Gobble within six months of exporting devices to the U.S. You will be advised of the timing of FDA's inspection schedule.

Gobble has an ongoing responsibility to conduct internal self-audits to assure you continue to maintain conformance with the Quality System Regulation.

If you have any questions regarding this correspondence, or need further assistance, please contact me at (301) 594-4595 or FAX (301) 594-4636.

Sincerely yours,

31 AUG 2000

Wayne Q Miller

Wayne Q. Miller
Consumer Safety Officer
General Surgery Devices Branch
Division of Enforcement I
Office of Compliance
Center for Devices and
Radiological Health

SOHAIL KAMAL
COUNTERSIGNED

Assistant Secretary

The Sialkot Chamber of Commerce & Industry

