[redacted]

Ahsan (U.K.) Limited

CE Marking Certification

Being Representative Organization, we hereby certify, that

M/s Weldon Industries (Pvt.) Ltd.

P. O. Box 584, Sialkot, Pakistan.

The manufacturer of Class I Medical Devices, have fulfilled all the formalities of declaration and registration, as per council directive 93/42/EEC with Medical Device Agency (MDA) – UK regarding the CE Marking vide MDA letter No. CA 005731 dated 24th August, 1999; and is valid till notified otherwise by MDA.

Muhammad Saleem Ahsan
Managing Director

September 20, 1999

REPRESENTATIVE ORGANIZATION FOR HEALTH & SAFETY IN ACCORDANCE WITH BRITISH, EUROPE & INTERNATIONAL STANDARDS

U.K. Office:
Bow Triangle Business Center
Unit # 22, Eleanor Street,
London E3 4UR
Tel: 00 44 (0) 20-8981-4845
Fax: 00 44 (0) 20-8980-8791

CE Marking

Pakistan Office:
Ahsan Chamber, 8-Syed Mauj Darya (Edward) Road, Lahore
Tel: 00 92 (0) 42 7312172
Fax: 00 92 (0) 42 7239612
E-mail: saiso@brain.net.pk

TÜV CERT

CERTIFICATE

The TÜV CERT Certification Body of TÜV Anlagentechnik GmbH
TÜV Rheinland Group

certifies in accordance with TÜV CERT procedures that

Weldon Industries (Pvt.) Ltd.
Near Small Industrial Estate
Shahabpura, Sialkot
Pakistan

has established and applies a quality management system for

Manufacture, Import & Export of Surgical, Dental, Eye, Veterinary, Manicure Instruments and all sorts of Scissors

An audit was performed, Report No. **031574**.
Proof has been furnished that the requirements according to

DIN EN ISO 9001:2000

are fulfilled. This certificate is valid in conjunction with the main certificate until **2007-02-23**.
Certificate Registration No. **01 100 031574/1**

COUNTERSIGNED
04/03/04
ARMGHAN HAFEEZ
Assistant Secretary
The Sialkot Chamber of Commerce & Industry

DAR TGA ZM-20-96-00

Cologne, 2004-02-24

TÜV CERT Certification Body of TÜV Anlagentechnik GmbH

TÜV TÜV Rheinland Group

www.tuv.com

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

SEP 1 2004

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

Mr. Waqar Amin
Chief Executive
Weldon Ind (Pvt.) Ltd.
Near S.I.E. P.O. Box 584 Shahab Pura Road
Sailkot-Pakistan 51310

and

Mr. Shakeel Baig
International Quality Management Consultants
Talwara Mughlan
Sialkot-Pakistan

Dear Messrs. Amin and Baig:

This is to acknowledge receipt of an August 10, 2004, letter from Mr. Shakeel Baig certifying the compliance of Weldon Ind (Pvt.) Ltd. (Weldon) 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.

The quality system audit report states that Weldon manufactures both single use and re-useable surgical instruments. Based on our review of the audit results and certification, Weldon has been placed on Attachment A of Import Alert #76-01. You may begin exporting both single use and re-useable surgical instruments 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.