

Diana Limited  
Davina House  
137-149 Goswell Road  
London  
EC1 7ET

Our Ref: CA 000964  
Direct Line: 0171 972 8318  
Direct Fax: 0171 972 8112

1 July 1997

Dear Sir/Madam,

**MEDICAL DEVICES REGULATIONS 1994: REGULATION 14**  
**Registration of Persons Placing Medical Devices on the Market**

Thank you for informing the Competent Authority of the company's details and for supplying the medical device information relating to the products manufactured by Towne Brothers (Pvt.) Ltd of Pakistan. Your registration has been recorded on the understanding that: —

**For Manufacturers of Class I medical devices, Assemblers, and Sterilisers**

You are now operating under the Medical Devices Directive and the 1994 Regulations for the products you asked us to register, by fully complying with the essential requirements, CE marking those products or labelling them as such.

**For Manufacturers of Custom-made devices**

You are ready to claim compliance with the Directive and Regulations and are manufacturing custom-made devices in accordance with their requirements.

**If you are not yet complying with the Regulations**

You should inform us so that we can remove your registration. The transitional period applies until 13 June 1998, when you believe that you meet the requirements of the Regulations, please re-apply for registration.

---

The information you provided has been recorded against the reference number shown at the top of this letter. Please use this in all future correspondence and communications.

This acknowledgement includes a record made from the information you supplied. Please check and inform us of any incorrect details. In cases where no generic code names were used, names, other than those you provide, may have been recorded. In these cases please consider if the names used would

cover your devices. Any changes we have made are intended to establish an acceptable standard terminology for data reference purposes only. Please inform us if we have omitted any range of devices that you notified.

From time to time, the coding of devices will be updated, if any changes are made to your records, we will write and inform you.

Please remember to inform us of any changes to:

- the company information
- additional range of devices
- discontinuation of a range of devices.

Please use RG2, the Registration form, to tell us about any of these changes.

Thank you for registering, and please check the following information:

Class I Devices

Dental Instruments; Re-Usable, Non-Powered

Yours sincerely



Miss A I Davis

(on behalf of the Competent Authority (UK))



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

DEC 06, 1994

**VIA FEDERAL EXPRESS**

Mr. Zahid Rafique  
Director  
Towne Brothers (PVT.) Ltd.  
52-B, Small Industries Estate  
Sialkot, Pakistan

and

Mr. William D. Curtin, RAC  
Curtin & Associates International  
1200 East Street  
Dedham, Massachusetts 02026

and

Mr. Abdul Ghafoor  
Towne International, Inc.  
717 E. Ordnance Road, #206  
Baltimore, Maryland 21226

Dear Messrs. Rafique, Curtin, and Ghafoor:

This acknowledges receipt of your October 25, 1994, letter requesting that Towne Brothers (PVT.) Ltd. (Towne Brothers) be removed from Attachment A of Import Alert #76-01 and placed on Attachment B of Import Alert #76-01. The letter provided documentation that Towne Brothers entered five stainless steel surgical instrument shipments into the United States (U.S.), sampled and laboratory tested those five shipments, and fulfilled the sampling and testing requirements of Import Alert #76-01.

Our office reviewed the documentation for the five shipments entered into the U.S. (sample numbers 1966391, 1965912, 1966248, 1966249, and 1965643). Included in the request was the entry detention paperwork, the entry release paperwork based on laboratory test results, the laboratory test results of each shipment, and summaries of all the test data. Sufficient information exists to evidence that Towne Brothers is purchasing raw steel in conformance with ASTM F899-84, and that the surgical instruments manufactured from that raw steel meet the requirements of ASTM F899-84.

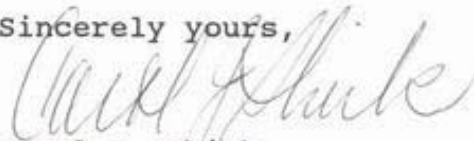
Based on the above information, Towne Brothers is removed from Attachment A on Import Alert #76-01. Towne Brothers will be placed on Attachment B of Import Alert #76-01. All

Page 2 - Messrs. Zahid Rafique, William D. Curtin, and  
Abdul Ghafoor

shipments will be entered into the U.S. free of the requirements under Attachment A of Import Alert #76-01, including detention, sampling, and laboratory testing. Please be advised that all Food and Drug Administration (FDA) district offices often choose to periodically audit, sample, and/or laboratory test any shipments as they are entered into the U.S. The placement of Towne Brothers on Attachment B does not relieve the firm from the possibility of being audited, sampled, and laboratory tested at intervals by the FDA.

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

Sincerely yours,



Carol J. Shirk  
Consumer Safety Officer  
General Surgery Devices Branch  
Division of Enforcement I  
Office of Compliance  
Center for Devices and  
Radiological Health

Certificate GB00/51815

The management system of

## Towne Brothers (Private) Limited

52-B Industrial Estate, P.O. Box 108, Sialkot, Pakistan

has been assessed and certified as meeting the requirements of

### ISO 9001:2000

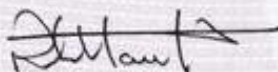
For the following activities

**Design and manufacture of custom made surgical and dental instruments. Manufacture and export of surgical and dental instruments.**

Further clarifications regarding the scope of this certificate and the applicability of ISO 9001:2000 requirements may be obtained by consulting the organisation

This certificate is valid from 21 August 2003 until 21 August 2006  
Issue 2. Certified since 21 August 2000

Authorised by



SGS United Kingdom Ltd Systems & Services Certification  
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK  
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com

SGS 9001-2 01 0303

Page 1 of 1



Certificate GB00/51814

The management system of

## Towne Brothers (Private) Limited

52-B Industrial Estate, P.O. Box 108, Sialkot, Pakistan



has been assessed and certified as meeting the requirements of

## ISO 13485:2003

For the following activities

**Design and manufacture of custom made surgical and dental instruments. Manufacture and export of surgical and dental instruments.**

This certificate is valid from 21 August 2003 until 21 August 2006  
Issue 2. Certified since 21 August 2000

Authorised by

A handwritten signature in black ink, appearing to read "D. Mant", is written over a faint, circular watermark of a globe.


SGS United Kingdom Ltd Systems & Services Certification  
Rossmore Business Park Ellesmere Port Cheshire CH65 3EN UK  
t +44 (0)151 350-6666 f +44 (0)151 350-6600 www.sgs.com



SGS 13485-2 0803

Page 1 of 1



(IBAR CODE)  *9613083*	DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>ANNUAL REGISTRATION OF DEVICE ESTABLISHMENT</b>	
<b>REGISTERED ESTABLISHMENT INFORMATION 9613083</b> TOWNE BROTHERS (PVT.), LTD. 52-B INDUSTRIAL ESTATE SIALKOT 51310 PAKISTAN	<b>A Type of Submission (mark one X only)</b> <input checked="" type="checkbox"/> No change <input type="checkbox"/> Correction <input type="checkbox"/> No Longer Device Establishment <input type="checkbox"/> Out of Business <b>B CORRECTIONS TO REGISTERED ESTABLISHMENT INFORMATION</b> Establishment Name Number and Street Number and Street City State ZIP/Postal Code Foreign State Country	
<b>ESTABLISHMENT TYPES (If information below is inaccurate, correct in column to right)</b> MANUFACTURER	<b>C CORRECTIONS TO ESTABLISHMENT TYPE (To correct, mark X all which apply)</b> <input type="checkbox"/> A Repackage and/or Relabel <input type="checkbox"/> B Specialized Device <input type="checkbox"/> C Contract Manufacturer <input type="checkbox"/> M Manufacturer <input type="checkbox"/> D Small Business/Manufacturer <input type="checkbox"/> E Manufacturer <input type="checkbox"/> F Contract Distributor <input type="checkbox"/> G Representative <input type="checkbox"/> H Foreign Supplier	
<b>OWNER / OPERATOR INFORMATION 9020929</b> TOWNE BROTHERS (PVT.), LTD. 52-B INDUSTRIAL ESTATE P.O. BOX 108 SIALKOT 51310 PAKISTAN 92-432-555334,6	<b>D CORRECTIONS TO OWNER / OPERATOR INFORMATION</b> Business Name Number and Street Number and Street City State ZIP/Postal Code Foreign State Country Phone No. ( ) Ex) Owner/Operator Number	
<b>OTHER BUSINESS TRADING NAMES</b>	<b>E CORRECTIONS TO TRADING NAMES (If name on left has errors, write corrected name on line to its right. If no longer used, write "DELETE". Write new names last, preceded by an asterisk.)</b>	
<b>OFFICIAL CORRESPONDENT INFORMATION</b> MR. HOWARD WAX HU-FRIEDY MFG. CO., INC. 3232 NORTH ROCKWELL ST. CHICAGO, IL 60618 PH: (773) 975-6100	<b>F CORRECTIONS TO OFFICIAL CORRESPONDENT</b> Name of Individual Business Name Number and Street Number and Street City State ZIP/Postal Code Foreign State Country Phone No. ( ) Ex) FAX No. ( ) Email Address	
<b>G SIGNATURE OF OFFICIAL CORRESPONDENT</b> 	<b>TITLE OF OFFICIAL CORRESPONDENT</b> CEO <b>DATE SIGNED</b> 10-14-02 <b>TYPED OR PRINTED NAME OF OFFICIAL CORRESPONDENT</b> HOWARD WAX	
Form FDA 2891a (5/02)		Part 2 - Complete and Return 051667 FOR: 2003 Form Approved: GMS, No. 9910-0087 Expiration Date: March 31, 2005

COPY



No. 6 (45-1) / 91  
675  
Date 27-4-91

# Government of Pakistan

## EXPORT TRADE CONTROL

*This is to certify that*

Export Registration No. W 010833 issued to  
Messrs Towne Brothers (Pvt) Ltd.

Address P.O. Box No. 108 Sialkot

has been renewed for the year 1991 to 1995 for the  
following commodities.

1. \_\_\_\_\_
2. \_\_\_\_\_
3. \_\_\_\_\_
4. \_\_\_\_\_
5. \_\_\_\_\_
6. \_\_\_\_\_
7. \_\_\_\_\_
8. \_\_\_\_\_

*W. M. P.*  
**Mohammad Tariq Pervaiz**  
DEPUTY CONTROLLER  
IMPORTS & EXPORTS  
SIALKOT.

*S. M. Mattu*  
(S. M. Mattu)  
CHIEF CONTROLLER OF  
IMPORTS AND EXPORTS

*P.T.O.*



T.C.No:131 Rs. 500/-

27.12.95 NBP

Renewed upto 31-12-2000.

*(Handwritten signature)*  
(Rehmat ur-Rehman)  
Executive Officer,  
Export Promotion Bureau  
Govt. of Pakistan, Sialkot.



M/S: TOWNE BROTHERS (PVT) LTD  
W-010833 T.C.NO:105 Rs:500/-  
19.12.2000  
RENEWED UP TO 31.12.2005/-

*(Handwritten signature)*  
(Rehmat-ur-Rehman)  
Assistant Director  
EXPORT PROMOTION BUREAU  
GOVT. OF PAKISTAN, SIALKOT.

Book No. **A 05190**

H-0212

Serial No. **A 518971**

# MEMBERSHIP CERTIFICATE

*(issued in pursuance of clause 23 of the Registration (Importers and Exporters) Order, 1952)*

Name & address of Chamber



The Sialkot Chamber Of Commerce & Industry

Share - E - Aiwani - E - Sanat - O - Tijarat

P. O. Box No. 1870 Sialkot - Pakistan

*(Affiliated with the Federation of Pakistan Chambers of Commerce & Industry)*

M/S: TOWNE BROTHERS(PVT) LTD

**CERTIFIED** that

*(name and address of importer/exporter)*

P.O. BOX: 108, 52-B, S.I.E., SIALKOT

\* Import Registration No. W/22306 Export Registration No. W/010833

is a member of this Chamber  
Association

**THIS CERTIFICATE** shall be valid upto the 28-02-2005 unless  
*(date)*  
otherwise notified to the Import/Export Licensing authority/Scheduled Bank  
concerned.



Given on this 16TH day of FEB 2004

Signature of Secretary

*Arif Hafeez*  
ARIFGHAN HAFEEZ  
ASST. SECRETARY

Countersigned by

*M. J. Khan*  
*(Name and Designation)*

\* Import/Export Registration No. to be given if registration already obtained.

Book No. A 05595

Serial No. A 559445

# MEMBERSHIP CERTIFICATE

(issued in pursuance of clause 23 of the Registration (Importers and Exporters Order, 1952)

T-002

Name & address of ~~XXXXX~~ The Surgical Instrument Manufacturers  
Association Association of Pakistan, Marala Road, Sialkot

(Affiliated with the Federation of Pakistan Chambers of Commerce & Industry)  
Karachi - Pakistan

CERTIFIED that M/s Towne Brothers (Pvt) Ltd

(name and address of importer/exporter)

52-B, S.I.E, P.O.Box: 108, Sialkot

\* Import Registration No. \_\_\_\_\_ Export Registration No. \_\_\_\_\_

is a member of this ~~XXXXX~~  
Association

*THIS CERTIFICATE* shall be valid upto the 30-06-2005 unless  
(date)  
otherwise notified to the Import/Export Licensing authority/ Scheduled Bank  
concerned.



Given on this 03rd day of July 2004

Signature of Secretary

Chairman

Secretary

The Surgical Instrument Manufacturers

Countersigned by

Association of Pakistan, SIALKOT

(name and designation)

\* Import/Export Registration No. to be given if registration already obtained.



# THE SIALKOT CHAMBER OF COMMERCE & INDUSTRY

P.O.Box 1870, Shahrah-E-Aiwan-E-Sanat-O-Tijarat, Sialkot – 51310, Pakistan  
Tele # +92-432-261881, 261882, 261883, Gram:Commerce, Fax # +92-432-268835, 267919  
Website: www.scci.com.pk, E-Mail: scci@skt.comsats.net.pk, scci@brain.net.pk

Ref.AS1507 //MF

Dated 15.07.2004

## **FREE SALES CERTIFICATE TO WHOM IT MAY CONCERN**

We hereby certify that the Dental, Orthodontic, Surgical, Ophthalmic and Electro-Medical Instruments as described in the attached catalogues are manufactured by Towne Brothers (Pvt) Ltd, P.O. Box. # 108, 52-56 B, Small Industrial Estate, Sialkot-51340 Pakistan and are lawfully sold / legally distributed in Pakistan in accordance with the statutory requirements and are being exported throughout the world.

This certificate is being issued on the specific request of the member firm.

  
Armghan Hafeez  
Assistant Secretary

A.Rauf



ISO 9002 CERTIFIED



- Recognized By The Government Of Pakistan
- Affiliated With The Federation Of Pakistan Chambers Of Commerce & Industry

Ref: SIMAP-T02-023

July 13, 2004

## FREE SALES CERTIFICATE

### To Whom It May Concern

This is to certify that M/s. Towne Brothers (Pvt.) Ltd., 52-56B, Industrial Estate, Sialkot – Pakistan is a bonafide member firm of this Association with membership # T-02.

According to the present regulations of the Government of Pakistan, the products described below may be freely distributed in Pakistan and can be exported without any regulatory permission, statutory requirement. These products are lawfully sold in Pakistan and are legally distributed around the world.

#### **Names of the Products:**

- Dental Instruments
- Orthopedic Instruments
- Surgical Instruments
- Ophthalmic Instruments
- Electro-Medical Instruments

#### **Name of the Manufacturer:**

M/s. Towne Brothers (Pvt.) Ltd.,  
52-56B, Industrial Estate,  
Sialkot - 51340, Pakistan

M/s. Towne Brothers (Pvt.) Ltd. is in compliance with the ISO-9001 (2000), ISO-13485 (2003), CE Comply with Essential Requirements of the 93/42 EEC Directive concerning Medical Devices and cGMP.

This certificate is issued on the specific request of the member company.

**Muhammad Umer**  
Secretary



### The Surgical Instrument Manufacturers Association of Pakistan Sialkot.

Near Sublime Chowk, Marala Road, Sialkot - Pakistan.  
Tel: 0092-554890, 563014, 562940  
Fax: 0092-432-554217  
E-mail: sima@brain.net.pk  
simap@cyber.net.pk  
URL: www.simap.org.pk

# OFFICE OF DISTRICT HEALTH OFFICER SIALKOT

PHONE: 586439



D.O. NO. 5471

DATE 21-07-2004

## FREE SALES CERTIFICATE

### To Whom It May Concern

This is hereby certified, according to the present regulation of Government of Pakistan, the products described below may be freely distributed in Pakistan and can be exported without any regulatory permission, statutory requirements. These products are lawfully sold in Pakistan and are legally distributed around the world.

Manufacturing company is in-compliance with ISO-9001 (2000), ISO-13485 (2003), CE comply with the Essential Requirements of the 93/42 EEC Directive Concerning Medical Devices and cGMP (FDA-USA).

This certificate is being issued on the specific request of the member firm.

Name of the Products;

- *Dental Instruments*
- *Orthodontic Instruments*
- *Surgical Instruments*
- *Ophthalmic Instruments*
- *Electro-Medical Instruments*

Name of the Manufacturer;

**Towne Brothers (Pvt) Ltd**  
52-56B, Industrial Estate,  
Sialkot-51340-Pakistan

On and Behalf of

**District Officer (Health)**  
Sialkot - Pakistan



# Sialkot Material Testing Laboratory

NEAR SUBLIME CHOWK, MARALA ROAD, SIALKOT-51310-PAKISTAN.

TEL: 0092-432-562818 FAX: 0092-432-554217

A JOINT VENTURE OF EXPORT PROMOTION BUREAU MINISTRY OF COMMERCE GOVT. OF PAKISTAN & SIMAP

SIMTEL/PD/ 322/2004

July 20, 2004

## ANALYTICAL / TEST REPORT

In respect of : *Towne Brothers Private Limited Sialkot*  
 Sample received from : *Representative*  
 Reference No. : *TWB/2004*  
 Dated : *17-07-2004*  
 Name of the sample : *TWB-L*  
 Type/Grade of Material : *AISI-410*  
 Specification against which tested : *ASTM. 899-95*  
*Analytical Results Got on Direct Emission Spectrometer*

*Sialkot  
Material  
Testing  
Laboratory*

Results are in percentage:

	Cr .....	13.329		
C .....	0.152		Mn .....	0.287
P .....	0.023		S .....	0.007
Si .....	0.198		Ni .....	0.171

This analytical/test report is based solely on the particular sample(s) supplied by the party and should not be reproduced in part.

Sampling has not been performed by the SIMTEL and the SIMTEL does not accept responsibility that the sample(s) supplied is/are truly representative sample(s) of any batch or stock or entire production.

While the SIMTEL agrees to take every reasonable precaution to ensure validity of its test results, it assumes no liability for the accuracy thereof beyond the amount of the fee charged for the analysis/test.

The party shall assume full responsibility for the ethical use of the results in the analysis/test reports and the laboratory shall be held free from any and all claims which may result from the use of such data by the party or others.

After completion of the report the sample will be preserved for three month until negotiated otherwise.

*Kh. Nazir Yasin Butt*  
Project Director





# Sialkot Material Testing Laboratory

NEAR SUBLIME CHOWK, MARALA ROAD, SIALKOT-51310-PAKISTAN.  
TEL: 0092-432-562818 FAX: 0092-432-554217

A JOINT VENTURE OF EXPORT PROMOTION BUREAU MINISTRY OF COMMERCE GOVT. OF PAKISTAN & SIMAP  
**SIMTEL/PD/ 321/2004**

July 20, 2004

## ANALYTICAL / TEST REPORT

In respect of : *Towne Brothers Private Limited Sialkot*  
 Sample received from : *Representative*  
 Reference No. : *TWB/2004*  
 Dated : *17-07-2004*  
 Name of the sample : *TWB-S*  
 Type/Grade of Material : *AISI-420*  
 Specification against which tested : *ASTM. 899-95*  
*Analytical Results Got on Direct Emission Spectrometer*

*Sialkot  
Material  
Testing  
Laboratory*

### Results are in percentage:

	Cr .....	13.295		
C .....	0.217		Mn .....	0.546
P .....	0.021		S .....	0.005
Si .....	0.401		Ni .....	0.169

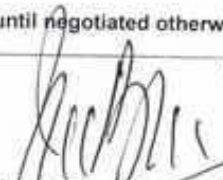
This analytical/test report is based solely on the particular sample(s) supplied by the party and should not be reproduced in part.

Sampling has not been performed by the SIMTEL and the SIMTEL does not accept responsibility that the sample(s) supplied is/are truly representative sample(s) of any batch or stock or entire production.

While the SIMTEL agrees to take every reasonable precaution to ensure validity of its test results, it assumes no liability for the accuracy thereof beyond the amount of the fee charged for the analysis/test.

The party shall assume full responsibility for the ethical use of the results in the analysis/test reports and the laboratory shall be held free from any and all claims which may result from the use of such data by the party or others.

After completion of the report the sample will be preserved for three month until negotiated otherwise.

  
- Kh. Nazir Yasin Butt  
Project Director

