Safeguarding public health

MHRA

Our Ref: CA 009913

Asim Majeed Shaikh
38 Parkville Road
Didsbury Manchester
M20 4UP
United Kingdom

23 August 2007

Dear Mr Shaikh,

MEDICAL DEVICES REGULATIONS 2002: REGULATION 19
Registration of Persons Placing General Medical Devices on the Market

Thank you for informing the Competent Authority of the details of ***Manufacturers*** **Name:- Ammad Surgical)** located at **Manufacturers Address:- 41-B Commercial Area Cavairy Ground Lahore Cantt Pakistan** for whom you are acting as the authorised representative and for supplying the medical device information.

Your registration has been recorded based on your declaration that you have determined that the device(s) fall within the definition of "medical device", and that you have classified it/them as falling within Regulation 19 taking into account the intended purpose(s) and mode(s) of action. In accepting your registration, I should make clear that the Competent Authority does not examine each individual notification and therefore cannot and does not necessarily endorse these determinations. Neither does this letter represent any form of accreditation or approval by the UK Competent Authority.

Your registration is based upon your declaration on the RG2 form and means that:

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

You should now be operating under the Medical Devices Directive and the above 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 should be ready to claim compliance with the Directive and Regulations and should be manufacturing custom-made devices in accordance with their requirements.

If you stop placing devices on the market or if you are not complying with the Regulations you should inform us so that we can amend our records. You should be aware that it is an offence to place on the market CE marked devices that do not comply with the regulations.

The information you provided has been recorded against the reference number shown at the top of this letter, which we ask you to quote in all future correspondence and communications.

Please inform us of any changes to:

- the company information
- additional generic groups of devices (not individual products within an existing generic group)
- discontinuation of a generic group of devices.

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

Thank you for registering the following generic groups of devices:

Class I Devices:

Surgical Instruments (Re-Usable And Non-Powered)
Surgical Instrument Accessories
Dental Instruments (Re-Usable & Non-Powered)

Custom Made Devices:

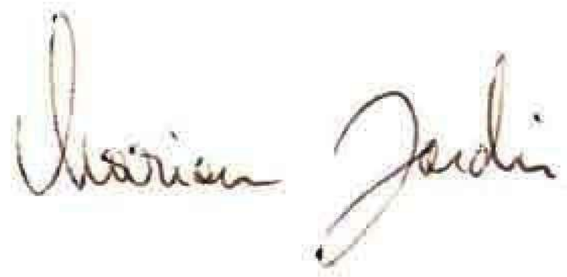
None

Products Covered By Article 12:

None

Should you have any queries regarding your registration please do not hesitate in contacting us.

Yours sincerely



Marion Jordis

Regulatory Affairs Administrator

Tel: 020 7084 3149

Fax: **020 7084 3107**

Email: marion.jordis@mhra.gsi.gov.uk

The decision based on your consultant certification will remain in effect until such time as FDA is able to visit Lahore, Cantt, 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, Ammad Surgical, including the possibility of removal from Attachment A.

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

Ammad Surgical 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 Brenda Pope at (240) 276-0115 or FAX (240) 276-0114.

Sincerely yours,

Thomas C. Knott
Chief
General Surgery Devices Branch
Division of Enforcement A
Office of Compliance
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
9200 Corporate Blvd
Rockville, MD 20850

FEB 20 2008

Mr. Ammad Nadim
Chief Executive Officer (CEO)
Ammad Surgical
41-B Commercial Area Cavalry Ground
Lahore, Cantt - Pakistan

and

Mr. Shakeel Baig
Managing Partner
International Quality System Consultants
Talwara Mughlan
Sialkot, Pakistan

Dear Messrs. Nadim and Baig:

This is to acknowledge receipt of an October 1, 2007, letter from Mr. Shakeel Baig certifying the compliance of Ammad Surgical 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 consultant certification confirmed that a quality system audit of Ammad Surgical was performed September 14, 2007 and a corrective action plan was implemented and verified on September 27, 2007.

The quality system audit report states that Ammad Surgical manufactures surgical instruments. Based on our review of the audit results and certification, Ammad Surgical has been placed on Attachment A of Import Alert #76-01 (Detention without Physical Examination of Surgical Instruments). 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 Ammad Surgical, 41-B Commercial Area Cavalry Ground, Lahore, Cantt - Pakistan. In the event the manufacturing name and/or address change, FDA requests that notification be immediately forwarded to this office. 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 Surgical Instruments Manufacturers Association of Pakistan

Ref: SIMAP/ A294 / 1009

July 25, 2015

FREE SALES CERTIFICATE

It is to certify that **M/s. Ammad Surgical**, 41-B Commercial Area, Cavalry Ground, Lahore-Pakistan is one of the bonafide member firm of The Surgical Instruments Manufacturers Association of Pakistan (SIMAP).

The company is registered with this Association bearing membership No.**A294 since 2009.** The Company is Manufacturers & Exporters of Surgical, Dental, Manicure & Pedicure, Veterinary instruments as per statutory requirement

They are permitted to produce and sell freely their products in Pakistan and abroad.

The certificate is issued on specific request of the firm.

Muhammad Amjad
Secretary General

Near Sublime Chowk, Marala Road, Sialkot - Pakistan. Ph: 0092-52-3554890, 3562940 Fax: 0092-52-3554217
E-mail: info@simap.org.pk URL: www.simap.org.pk

- Recognized By The Government of Pakistan.
- Affiliated with Federation of Pakistan Chamber of Commerce & Industry

The Surgical Instrument Manufacturers Association of Pakistan

Ref: SIMAP-A294-234

November 7, 2009

FREE SALE'S CERTIFICATE

It is to notify that **M/s. Ammad Surgical, 41-B, Commercial Area Calvary Ground, Lahore- Pakistan** is one of the bona fide members of this Association with membership no. A-294. The company manufactures & exports of Surgical, Dental, and Veterinary Instruments as per statutory requirement.

They are permitted to produce and freely sell their Products in Pakistan and world over.

The certificate is issued on specific request of the firm.

Abdul Waheed
Secretary General

Near Sublime Chowk, Marala Road, Sialkot - Pakistan. Tel: 0092-52-3554890, 3562940 Fax, 0092-52-3554217
E-mail: info@simap.org.pk URL: www.simap.org.pk

Certificate of Registration

The Governing Board of
Q.A. International Certification Limited
hereby grants to:

AMMAD SURGICAL

Registration No.: QAIC / PK / 3530 - B

(hereinafter called the Registered Company) the right to be listed in the Directory of Registered Companies in respect of the services listed below. These services shall be offered by the Registered Company at or from only the address given below in accordance with the quality management system in Compliance with the Requirements of ***ISO 13485:2016.***

Address to which this Certificate refers:

41-B Commercial Area Cavalry Ground Lahore Cantt - Pakistan

Approved Scope to which this Certificate refers:

Manufacturer of Non-Active Surgical and Dental Instruments.

(Please note that the above scope represents the certified activity of the named organisation and as such, the organisation may undertake additional activities that are not covered under this certification).

Signed for and on behalf of the Board

CHIEF EXECUTIVE

SCHEME MANAGER

Certificate Issue Date: *18th March 2020* - **Certificate Renewal Before**: *28th February 2021*
Date of Initial Registration: *29th February 2016* - **Re-Certification Before**: *28th February 2022*

This Certificate of Registration is granted subject to the Regulations approved by the Board.

QA INTERNATIONAL

Q.A. International Certification Ltd.
Dudley Court
Dudley Road
Darlington
United Kingdom
DL1 4GG

Tel: +44 (0)1325 384272
Fax: +44 (0)1325 480980
www.qai.co.uk

The use of the Accreditation Mark indicates accreditation in respect of those activities covered by the accreditation certificate number 046.

Certificate of Registration

The Governing Board of
Q.A. International Certification Limited
hereby grants to:

AMMAD SURGICAL

Registration No.: QAIC / PK / 3530 - A

(hereinafter called the Registered Company) the right to be listed in the Directory of Registered Companies in respect of the services listed below. These services shall be offered by the Registered Company at or from only the address given below in accordance with the quality management system in compliance with ***ISO 9001:2015.***

Address to which this Certificate refers:

41-B Commercial Area Cavalry Ground Lahore Cantt- Pakistan

Approved Scope to which this Certificate refers:

Manufacture of Surgical and Dental Instruments.

(Please note that the above scope represents the certified activity of the named organisation and as such, the organisation may undertake additional activities that are not covered under this certification).

Signed for and on behalf of the Board

CHIEF EXECUTIVE

SCHEME MANAGER

Certificate Issue Date: *20th March 2020* - **Certificate Renewal Before**: *28th February 2021*
Date of Initial Registration: *29th February 2016* - **Re-Certification Before**: *28th February 2022*

This Certificate of Registration is granted subject to the Regulations approved by the Board.

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