Safeguarding public health

MHRA

Our Ref: CA007044

Mr Abdul Razzaq,
Black Smith Ltd
13 Church Fields Avenue
Hanworth
Middx
TW13 5PB
United Kingdom

17 May 2010

Dear Mr Razzaq,

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 change to the original notification dated 7/9/2001; *Manufacturers* **Name:- Zona Industries** located at **Manufacturers Address:- Pul Aik Aminabad Rd Sialkot Pakistan 51310** for whom you are acting as the authorised representative and for supplying the medical device information.

The change(s) to 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)
Dental Instruments (Re-Usable & Non-Powered)
Syringes (Hypodermic/Oral/Irrigation)
Dental Diagnostic Fibre Optic Handpieces
Handheld Dental Mirrors And Accessories
Electrodes/Transducers And Accessories
Stethoscopes
Endoscopes/Endoscopic Instruments And Accessories
Laryngoscopes/Otoscopes And Accessories
Bandages (Eg Support/Tubular/Adhesive/Plaster Of Paris/Cast Liners/Resin)
Cotton Wool/Gauze/Non Woven/PVA(Ribbons/Swab/Buds)
Hospital Beds And Patient Positioning Aids
Patient Hoists/ Transfer Aids And Accessories
Stretchers/Chairs/Hospital Trolleys (Patient Transport)
Ophthalmascopes/Retinascopes
Eye Speculums
Compression Hosiery/Garments
Umbilical Clamps/Tape
Surgical Instrument Accessories
Operating Tables And Accessories
Vaginal Speculums
Electrosurgical Accessories(e.g.Transient Invasive Electrodes,Footswitches)
Wheelchairs (Non-Powered) And Accessories
Nasal Speculum

Custom Made Devices:

None

Products Covered By Article 12:

None

Confidentiality

Please note that in accordance with Directive 2007/47/EC as of 21st March 2010 information on the registration of persons responsible for placing devices on the market will no longer be treated as confidential and the Competent Authority will provide third parties with information on the name and address of manufacturers and authorised representatives and their devices that have been registered. However the names of individuals, their telephone numbers and email addresses will remain confidential unless you have chosen to trade using personal details. This change only applies to medical devices and does not affect In Vitro Diagnostic devices registration, which remain confidentiality under Article 19 of the In Vitro Diagnostic Directive 98/79EC.

If your company name or that of a manufacturer that you represent is based on an individual's personal name it will be published unless you inform the MHRA that you would like the company name to remain confidential.

Likewise, if your company address or that of a manufacturer that you represent is the personal home address of an individual it will be published unless you inform the MHRA that you would like the company address to remain confidential.

Should you have any queries regarding your registration, please do not hesitate to contact us.

Yours sincerely

Barbara Clarke

Regulatory Affairs Administrator

Tel: 020 7084 3195

Fax: 020 7084 3112

Email: barbara.clarke@mhra.gsi.gov.uk

Certificate of Registration

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

ZONA INDUSTRIES

Registration No. : QAIC / PK / 871-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:13485:2003.

Address to which this Certificate refers :

Pul Aik, Aminabad Road, Sialkot-51310 - Pakistan

Approved Scope to which this Certificate refers.

Manufacturing of Inert Surgical, Dental, Manicure, Pedicure Instruments

Signed for and on behalf of the Board

CHIEF EXECUTIVE SCHEME MANAGER

Certificate Issue Date : *2nd April 2015* - **Certificate Expiry Date** : *14th March 2016.*
Date of Initial Registration :*10th May 2006* - **Re-assessment Date** : *14th March 2018*
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 4GA
Tel: +44 (0)1325 381222
Fax: +44 (0)1325 480000
www.qa-intl.com

Certificate of Registration

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

ZONA INDUSTRIES

Registration No. : QAIC / PK / 871-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 9001:2008.***

Address to which this Certificate refers :

Pul Aik, Aminabad Road, Sialkot-51310 - Pakistan

Approved Scope to which this Certificate refers.

Manufacturing of Surgical, Dental, Manicure, Pedicure Instruments and Fly Fishing Tools

Signed for and on behalf of the Board

CHIEF EXECUTIVE SCHEME MANAGER

Certificate Issue Date : *2nd April 2015* - **Certificate Expiry Date** : *14th March 2016*
Date of Initial Registration :*10th May 2006* - **Re-assessment Date** : *14th March 2018*
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 3GG

Tel: +44 (0)1325 384272
Fax: +44 (0)1325 480990
www.qai.co.uk