Certificate

The Governing Board of
Certlink Certification Services
hereby grants to:

F.A. NAJMMY INDUSTRIES

Certificate No: CL/PK/23737-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:
136-C Fatima Jinnah Road, S.I.E, Sialkot - Pakistan.

Approved Scope to which this Certificate refers:

Manufacturers and Exporters of Surgical, Dental, Veterinary, Beauty Care Instruments & Scissors.

(Further clarification regarding the Scope of this Certificate and the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization)

Signed for and on behalf of the Board

Digitally signed by Iarovoi Petru
Date: 2022.09.16 19:44:39 EEST
Reason: MoldSign Signature
Location: Moldova

SCHEME MANAGER

Certificate Issue Date: *15 February 2022* - **Certificate Expiry Date:** *14 February 2023*
Date of Initial Registration: *13 February 2020* - **Re-assessment Date:** *14 February 2024*
This Certificate of Registration is granted subject to the Regulations approved by the Board.

Certlink Certification Services.
Info@cert-link.com
www.cert-link.com

MHRA

Safeguarding Public Health

Medicines and Healthcare products Refulatory Agency

Market Towers
1 Nine Elms Lane London SW8 5NQ

General enquiries
Telephone: 020-7084 2100 Fax: 020-7084 2343
E-mail: info@mhra.gui.gov.uk

www.mhra.gov.uk

Direct line: 0207 084 3195

Direct Fax: 0207 084 3142

Eimail rob. Higgins@mhra.gui.gov.uk

Our ref. **CA 008893**

Mr D Iqbal
Blue Star Company
40, Thorncliffe Road
Norwood Green
Southhall
Middlesex
UB2 5RQ

09 October 2005

Dear **Mr. D Iqbal,**

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

Than you for informing the Competent Authority of the details of **Manufacturers Name:- F. A. Najmmy Industries)** located at **Manufacturers Address:- 136-C, Fatima Jinnah Road, Small Industrial Estate, Sialkot Pakistan** for whom you are acting as the authorized 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 Sterilizers
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 labeling 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 are communications.

Please inform us of any changes to:

- The company information
- Additional generic group 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:

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

Custom Made Devices:

None

Products Covered By Article 12:

None

Should you have any queries regarding your registration please contact us on the telephone number given at the top of this letter.

Yours sincerely

Rob Higgins