



Certification is conditional on maintaining the required performance standards throughout the certified period of registration
QA International Certification, Dudley Court, Dudley Road, Darlington, Co. Durham, DL1 4GG

The management system of Certificate Number **613143**
QAICL Ref: **PK/4043**

FIZZA SURGICAL INTERNATIONAL
Nargate Street, Jinnah Park Colony # 2, Sialkot - 51310, Pakistan

has been assessed and certified as meeting the requirements of

BS EN ISO 13485: 2016

Manufacturers and Exporters of Non-Active Re-useable Surgical and Dental Instruments & Single Use
Surgical Instruments around the Globe

Further clarifications regarding the scope of this certificate and the applicability of requirements may be obtained by consulting the certifier.

Valid from

Initial Certification: 07 April 2021
Latest Issue: 16 April 2024
Expiry Date: 06 April 2025
Recertification Before: 06 April 2027
subject to annual assessments

Authorised by

Mike Tims
Chief Executive Officer



www.qaicl.co.uk

Certificate issued by QA International Certification Limited

The validity and status of this certificate can be verified by using the UKAS CertCheck website at certcheck.ukas.com

CERTIFICATE OF COMPLIANCE

This is to certify, that the hereunder described items of Medical Devices Directive 93/42/EEC as amended by Directive 2007/47/EC have proven their conformity to the Safety and Health requirements of the Directive.

Manufactured by: **FIZZA SURGICAL INTERNATIONAL**

Address: Nesr Gate Street, Jinnah Park, Colony no. 2,
 Sialkot-51310, Pakistan

Products:

- | | | |
|------------------|---------------------|----------------------------|
| Scissors | Extracting forceps | Cement spatula |
| Forceps | Curretes | Bone instruments |
| Needle holders | Scalars | Wire mesh basket and trays |
| Retractors | Root elevators | Orthodontic instruments |
| Speculums | Mirror and handles | Hollowware instruments |
| Laryngoscope | Probes | Crown instruments |
| Dressing forceps | Impression trays | Filling instruments |
| Mouth gags | Implant instruments | Rubber dam instruments |

Classification: Class I, re-usable, non-powered and non-measuring devices (accordingly, to the Manufacturer's declaration)

The manufacturer's technical documentation of the product(s) has been reviewed and found to comply with requirements of the above Council Directive. With drawn up an EC declaration of conformity as per Annexure VII, module A of the product, you are therefore licensed to CE mark the product(s) listed above in accordance with Article 17 of the Medical Device Directive.

This certificate shall not be reproduced except in full and remain property of CNC Services to whom must be returned on request. This certificate does not imply assessment of the series-production of the product. The holder must inform CNC Services, of any substantial changes occurred in the product or process in order to examine whether this certificate remains valid. Certificate verification available at <https://www.cncservices.net/verification>



For CNC Services




Project Engineer

Date of Issue: 2nd April, 2024

Date of Expiry: 1st April, 2026

Certificate Number: **EC/4970/21**



Fizza Surgical International

Manufacturer of Quality Medical Instruments

DECLARATION OF CONFORMITY

Manufacturer Name: FIZZA SURGICAL INTERNATIONAL
Manufacturer Address: Nargate Street, Jinnah Park, Colony No 2, Sialkot-51310, Pakistan
Authorized Representative: Najam Ali
Name of Products: Surgical Instruments, Bone Surgery Instruments, Dental Instruments.
Classification: Class 1 , Classification Directive 93/42/EEC

This declaration of conformity is issued under the sole responsibility of FIZZA SURGICAL INTERNATIONAL. We hereby declare that the medical device(s) specified above meet the provision of the Directive 93/42/EEC for medical devices. This declaration is supported by the Quality System approval to ISO 9001 issued by CNC Services. All supporting documentation is retained at the premises of the manufacturer.

Signature:

Dated: 17-01-2022

Fizza Surgical International

Najaf Ali
Title: Proprietor
Fizza Surgical International



Proprietor

