

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, 2021

Date of Expiry: 1st April, 2024

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



Certificate of Registration



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

FIZZA SURGICAL INTERNATIONAL

Registration No.: QAIC / PK / 4043 – 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 the Requirements of ISO 13485:2016.

Address to which this Certificate refers:

Nargate Street, Jinnah Park Colony # 2, Sialkot – Pakistan

Approved Scope to which this Certificate refers:

Manufacturers of Non-Active Reusable Surgical and Dental Instruments & Single Use Surgical 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: 7th April 2021 - Certificate Renewal Before: 6th April 2022
Date of Initial Registration: 7th April 2021 - Re-Certification Before: 6th April 2024

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

QA INTERNATIONAL

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The use of the Accredited Mark indicates accreditation in respect of those activities covered by the accreditation certificate number 045.



Fizza Surgical International
Manufacturer of Quality Medical Instruments

Confirmation Letter

To:

**Center for Public Procurement in Healthcare
Republic of Moldova**

WHEREAS,

We **FIZZA SURGICAL INTERNATIONAL**, who are manufacturers of **Surgical Instruments**, having factories at Nesr Gate Street, Jinnah Park, Colony no.2, Sialkot-51310, Pakistan

confirm that Surgical Instruments, offered by company FPC SOGNO SRL on the Tender no. 21065142 from 09.11.2022, made of medical grade stainless steel **304, 316L, 410, 420 and 440** with following hardness of working parts (standard EN ISO 7153-1):

40-48 HRC - Lots no. 19, 37-40, 42, 44-46, 48-51, 63-65, 67-71, 82-90, 93-95, 97, 111-113, 142, 146.

50-58 HRC - Lots no. 3, 4, 6, 109, 110, 115, 116.

For FIZZA SURGICAL INTERNATIONAL,

FIZZA SURGICAL INTERNATIONAL

Partner

ALI HASSAN

Date: 07.11.2022