

Certificate. ER/2024/0001/01

Authorized Representative Article 11 MDR 2017/745 SRN: NL-AR-000039160

It is confirmed that LORCAN & FYON will act as the EU Representative for the following manufacturer:

FIZZA SURGICAL INTERNATIONAL

Nar Gate Street, Jinnah Park, Colony No. 2, Sialkot, 51310, Pakistan

FOR

Medical Device Products CLASS HISTED IN ATTACHED ANNEX 1

The Certificate will remain valid provided that the manufacturer complies with the EU REP Agreement, including its expiration.

The product liability rests with the manufacturer in accordance with applicable regulation and standards, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE Marking to all below mentioned models of the medical device. The product classes covered are in ATTACHED ANNEX 1.

> Date of Initial Registration: 08-03-2024 Certification Renewal: 07-03-2025 Certification Issued on: 08-03-2024

AUTHORIZED SIGNATORY



LORCAN & FYON B.V.







Lorcan & Fyon B.V. Europalaan 40, 3526KS Utrecht, The Netherlands Telephone: +31 30 808 3045 Fax: +31 30 808 3048 Email: info@lorcanandfyon.eu www.lorcanandfyon.eu



ANNEX 1 - PAGE 1/2:

List of medical devices under the scope of the agreement.

SURGICAL / DENTAL INSTRUMENTS

Bone Surgery Hemostatic Forceps Needle Holder Retractors Scissors Stomach Intestinal Instruments Thorax Lung **Urology Instruments** Tweezers Scalar Trays and Boxes Excavators Dental Needle Holder Wax and Modeling Carvers **Filling Instruments** Mirror and Handle Articulators Syringes Knives and Spatula **Gracey Curettes Impression Trays** Explorer Periodontal Instruments Hollowware **Endodontic Instruments**

AUTHORIZED SIGNATORY

LORCAN & FYON B.V.





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ANNEX1 - PAGE 2/2:

List of medical devices under the scope of the agreement.

SURGICAL / DENTAL INSTRUMENTS

Root Elevators Orthodontic Pliers Crown and Rubber Dam Instruments Extracting Forceps Implantology Instruments Hollowware Cotton Swab Forceps Diagnostic Instruments Dressing Forceps ENT Instruments Gynecology Instruments Laryngoscope

AUTHORIZED SIGNATORY

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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. ocds-b3wdp1-MD-1723448905042 / 21268240 from 17.09.2024, made of medical grade stainless steel 304, 316L, 410, 420, 440, and have autoclaving corrosion and thermal exposure resistance according to the ISO 13402.

For FIZZA SURGICAL INTERNATIONAL,



Nar Gate Street, Jinnah Park Colony No:2, Sialkot, Pakistan Tel:+92-52-4604164, E-mail: info@fizzasurgical.com Web: www.Fizzasurgical.com

Fax: +92-52-4580014 Najam.Ali@fizzasurgical.com



ISO 13485: 2016 ISO 9001:2015 **CEMARK GMP APPROVED**



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We confirm that Surgical Instruments, offered by company FPC SOGNO SRL on the Tender no. ocdsb3wdp1-MD-1723448905042 / 21268240 from 17.09.2024, 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

- Lot no. 52 (SC 02-827...829-03)
- Lot no. 58 (SC 02-12-03)
- Lot no. 60 (SC 02-15-02)
- Lot no. 71 (SC 02-110...112-04)
- Lot no. 117 (HF 04-100-01 / HF 04-85-01)
- Lot no. 119 (HF 04-91-01)
- Lot no. 124 (HF 04-141-05)
- Lot no. 125 (HF 04-141-06)
- Lot no. 149 (DF 03-335-04)
- Lot no. 172 (RT 11-370-01...03)

50-58 HRC

- Lot no. 28 (BS 14-896-02)
- Lot no. 29 (BS 14-896-03)
- Lot no. 30 (BS 14-896-04)
- Lot no. 31 (BS 14-895-04)
- Lot no. 75 (SC 02-882-01)

For FIZZA SURGICAL INTERNATIONAL,

Fizza Surgical International

ALI HASSAN



Date: 12.09.2024

Fax: +92-52-4580014 Najam.Ali@fizzasurgical.com



ISO 13485: 2016 ISO 9001:2015 **CEMARK GMP APPROVED**



Fizza Surgical International

Manufacturer of Quality Medical Instruments

Confirmation Letter

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WHEREAS,

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

confirm that Needle Holders, offered by company FPC SOGNO SRL on the Tender no. ocds-b3wdp1-MD-1723448905042 / 21268240 from 17.09.2024, has the following parameters of TC inserts (they are not expressly specified in the catalog):

Lot no. 159 (Ref. code NH 10-420-04 TC)

- TC jaw surface: 0.4mm pitch of serration
- Suture size: USP 4/0 USP 6/0

Lot no. 161 (Ref. code NH 10-305-05 TC)

- TC jaw surface: 0.5mm pitch of serration
- Suture size: USP 3/0

Lot no. 164 (Ref. code NH 10-325-01 TC / NH 10-305-03 TC)

- TC jaw surface: 0.5mm pitch of serration
- Suture size: USP 3/0

Lot no. 169 (Ref. code NH 10-420-04 TC)

Suture size: USP 5/0 – USP 6/0

For FIZZA SURGICAL INTERNATIONAL,

Fizza Surgical International

ALI HASSAN Date: 12.09.2024

Fax: +92-52-4580014 Najam.Ali@fizzasurgical.com



