



INDIAN FDA APPROVED



# *Austeofix Surgical Pvt. Ltd.*

## *A Perfect Fixation*

ISO 9001, ISO 13485, & F.D.A CDSKO APPROVED COMPANY WITH C.E MARKED PRODUCTS





# ***Austeofix Surgical Pvt. Ltd.***

## **About Us**

We, **Austeofix Surgical Pvt. Ltd.**, are working as a renowned Manufacturer and Suppliers of **Orthopedic Implants, Maxillofacial Implants, Spine Fixation Implants and Instruments** of exceptional quality. With experience of more than two decades in this domin, the Director of this company decided to start with its own brand "**Austeofix**" to bring forth high quality products at best prices. Available in various specifications, Our Quality proven range of Orthopedic Implants, Maxillofacial Implants, Spine Fixation Implants and Instruments distinguish us from others in this competitive marketplace,

We have assembled a team of experienced personnel which helps us in carrying out daily operations efficiently and smoothly. Our workforce comprises 25 individuals including administration, sales and marketing personnel. We have strategically placed our sales office in the centre of the city which makes communication with various authorities and rendering services to clients easy and hassle free.

We have acquired all the required certifications for Quality and Manufacturing Orthopedic Implants, Maxillofacial Implants, Spine Fixation Implants and Instruments like **ISO 9001: 2015, ISO 13485, CE Marking, And Manufacturing Drug License Approved By CDSCO ( FDA) India ..**



Single Pin Clamp 4.5 x 11 mm  
Cat No.: S.175.45.11  
Size.: Universal



Double Pin Clamp 4.5 x 11 mm  
Cat No.: S.175.45D.11  
Size.: Universal



Tube To Tube Clamp  
Cat No.: S.175.TTC  
Size.: Universal



Hybrid Clamp  
Cat No.: S.175.HC  
Size.: Universal



Hybrid Clamp 90 Deg.  
Cat No.: S.175.HC90  
Size.: Universal



Transverse Clamp  
Cat No.: S.175.TC  
Size.: Universal



Single Pin Clamp 3.5 x 4.0 mm For Forearm  
Cat No.: S.175.35.40  
Size.: Universal



Aesculap Clamp  
Cat No.: S.175.2540 , S.1754580  
Size.: Small. Large



Tubular Rod Dia 8.0 mm  
Cat No.: S.177.8150-8350  
Size.: 150 mm to 350 mm



Tubular Rod Dia 11.0 mm  
Cat No.: S.175.150-450  
Size.: 150 mm to 450 mm



Single Pin Distractor (M4) Sinle /Double Hole  
Cat No.: S.177.DSP.60-150  
Size. 60 mm to 150 mm :



Double Pin Distractor (M6) Doble Hole  
Cat No.: S.177.DD.150-350  
Size.: 150 mm to 350 mm



Link Joint ( Alpha , Beta Clamp)  
Cat No.:S.177.V. LJS, LJM, LJL  
Size.: Small , Medium, Large, X Large



Schanz Pins  
Cat No.: S.171.20-45  
Size.: 2.0 mm to 6.5 mm



Tapperd Schanz Screw  
Cat No.: S.173.625150- 640200  
Size.: 6x25x150, 6x25x200, 6x30x100, 6x32x200  
6x40x120, 6x40x200, 6x50x225



Knurled Rod Straight 2.0, 2.5, 3.0, 4.0 mm,  
Cat No.: S.177.KR.2-4  
Size.: 100 mm to 400 mm



Half Ring  
Cat No.: S.178.HR.120-240  
Size.: 120 mm to 240 mm



5/8 Ring  
Cat No.: S.179.58.100-220  
Size.: 100 mm to 220 mm



Omega Ring  
Cat No.:  
Size.: 120 mm to 240 mm



Italian Arch 90 Deg, 120 Deg  
Cat No.: S.180.90.140-200 , S.180.120.140-200  
Size.: 140 mm to 200 mm



Foot Ring  
Cat No.: S.186.FR.140-180  
Size.:140, 160, 180 mm



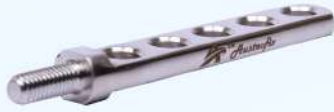
Threaded Rod 6 mm  
Cat No.: S.181.06.50-450  
Size.:50 mm to 450 mm



Hinges Male  
Cat No.: S.183.HM, S.183.HF  
Size.: Universal



Hinges Female  
Cat No.: S.183.HM, S.183.HF  
Size.: Universal



Post Male  
Cat No.: S.184.MP.2-5  
Size.: 2,3,4,5 hole



Post Female  
Cat No.: S.184.FP.2-5  
Size.: 2,3,4,5 hole



Oblique Support  
Cat No.: S.185.OS  
Size.: Universal



Short Connection Plate  
Cat No.: S.187.SCP.2-16  
Size.: 2 hole to 16 hole



Twisted Plate  
Cat No.: S.187.TP.1 - 6  
Size.: 1 Hole to 6 Hole



Connecting Bolts  
Cat No.: S.188.CB  
Size.: 10, 15, 20 mm



Nuts  
Cat No.: S.188.N.10  
Size.: 10 mm



Nylon Nut  
Cat No.: S.188.NN.10  
Size.: 10 mm



Square Nut  
Cat No.: S.188.SN  
Size.: Universal



Wire Fixation Bolt Cannulated  
Cat No.: S.188.WFBC  
Size.: Universal



Wire Fixation Bolt Slotted  
Cat No.: S.188.WFBS  
Size.: Universal



Conical Washer  
Cat No.: S.193.CW  
Size.: Couple



Spacing Washer Slotted / Spacing  
Cat No.: S.193.WS, S.193.W  
Size.: 1.8 mm



Wracho Cube For Tapperd Schanz Screw  
Cat No.:S.189.WC1-5  
Size.:1 Hole to 5 Hole



Threaded Socket  
Cat No.: S.189.TS.20-50  
Size.: 20 mm to 50 mm



Olive Wire Bayonet  
Cat No.:S.191.KWB15,18  
Size.:1.5 mm , 1.8 mm



Bayonet / Trokar Wire Plain  
Cat No.: S.190.KWB18  
Size.: 1.5 mm , 1.8 mm



Spanner  
Cat No.: S.195.10-11  
Size.:10 - 11



Box Spanner T Type  
Cat No.: AFOI349  
Size.: 10 mm



Schanz Pin Introducer D Type  
Cat No.:  
Size.:Univarsal



Box Spanner For Nuts & Wire Fixation Bolt  
Cat No.: AFOI348  
Size.:Univarsal



Wire Tensioner Mechanical  
Cat No.: S.194.WTO  
Size.:Univarsal



Wire Tensioner Graduated  
Cat No.: S.194.WTG  
Size.:Univarsal



**QUALITY MANAGEMENT SYSTEM**

## Certificate of Registration

This is to Certify That The Quality Management System of  
**AUSTEOFIX SURGICAL PVT. LTD.**


PLOT NO. 81, SOLITAIRE INDUSTRIAL PARK, PHASE 1,  
DEHMI KALAN, JAIPUR AJMER EXPRESS HIGHWAY,  
BAGRU, JAIPUR- 303007, RAJASTHAN, INDIA

*has been assessed and found to conform to the requirements of*  
**ISO 9001:2015**  
*for the following scope :*


DESIGN, MANUFACTURE AND SUPPLY OF VARIOUS TYPES  
OF TRAUMA (VARIOUS LOCKING AND NON LOCKING), SPINE,  
ARTHOPLASTY, ARTHROSCOPIC, MAXILLOFACIAL (DENTAL),  
CRANIO MAXILLOFACIAL, EXTERNAL FIXATORS AND  
VARIOUS TYPES OF ORTHOPEDIC SURGICAL INSTRUMENTS

Certificate No : **20DQGU5B**  
Initial Registration Date : 02/06/2020 Issuance Date : 02/06/2020  
Date of Expiry\* : 01/06/2021  
Date of Re certification : 02/06/2023

*[Signature]*  
DIRECTOR  
**ROHS Certification Pvt. Ltd.**

488, Middlesex Building, 25, Abchurch Lane, New Delhi - 110 001, India  
Phone : +91 11 47335522 | e-mail: info@rohs-certification.com | website: www.rohs-certification.com  
The Registration is now a Product Quality Certificate. Subject to successful completion of surveillance audits. This registration is non-transferable between  
Companies in the scope of ROHS and where when demanded



## CERTIFICATE

*This is to Certify that the*  
*Medical Device Quality Management System of*  
**AUSTEOFIX SURGICAL PRIVATE LIMITED**




PLOT NO. 81, SOLITAIRE INDUSTRIAL PARK, PHASE 1, DEHMI KALAN,  
JAIPUR AJMER EXPRESS HIGHWAY, BAGRU, JAIPUR - 303007,  
RAJASTHAN, INDIA

*has been independently assessed and is compliant with the requirements of:*  
**ISO 13485:2016**  
*(Medical devices - Quality management systems - Requirements for regulatory purposes)*  
*This certificate is applicable to the following scope of operations:*

DESIGN, MANUFACTURE, EXPORT AND SUPPLY OF ALL TYPES OF  
TRAUMA (ALL LOCKING AND NON LOCKING), SPINE, ARTHROPLASTY,  
ARTHROSCOPIC, MAXILLOFACIAL (DENTAL), CRANIO MAXILLOFACIAL,  
EXTERNAL FIXATORS AND ALL TYPES OF ORTHOPEDIC AND  
GENERAL SURGICAL INSTRUMENTS

Certificate No.: **SPC17M1226**      Date of Initial Registration: 29-04-2017  
Date of This Certificate: 01-06-2020  
Surveillance audit on or before: 28-04-2021  
Date of Re-Certification: 29-04-2023

*[Signature]*  
Authorised Signatory  
**SP Certification Limited**  
130, Old Street, London,  
EC1V9BD, U.K.  
Email: info@spcertification.co.uk  
www.spcertification.co.uk

Accredited by Accreditation Forum of International Standards [AFIST (UK) LTD.]  
9, Park View Road, Leeds, LS4 2LG, United Kingdom (UK), Email : info@afist.org, Website : www.afist.org  
The approval is subject to the company maintaining its systems to the required standards, which will be monitored by SPC.  
The Certificate remains the property of SPC and must be returned on request.  
To check validity of this certificate please visit [www.spcertification.co.uk](http://www.spcertification.co.uk) and [www.afist.org](http://www.afist.org)

**CERTIFICATE**



## CERTIFICATE

*Of Compliance*

This is to certify that the technical documentation has been independently assessed and  
compliant with the requirements of MDD directive 93/42/EEC

**Manufacturer**

Name : **AUSTEOFIX SURGICAL PRIVATE LIMITED**  
Address : **PLOT NO. 81, SOLITAIRE INDUSTRIAL PARK,  
PHASE 1, DEHMI KALAN, JAIPUR AJMER EXPRESS  
HIGHWAY, BAGRU, JAIPUR - 303007, RAJASTHAN, INDIA**

**Product Details** : **TRAUMA (ALL LOCKING AND NON LOCKING), SPINE,  
ARTHOPLASTY, ARTHROSCOPIC, MAXILLOFACIAL  
(DENTAL), CRANIO MAXILLOFACIAL, EXTERNAL  
FIXATORS AND ALL TYPES OF ORTHOPEDIC AND  
GENERAL SURGICAL INSTRUMENTS (AS PER  
ANNEXURE ATTACHED)**

**Applicable Standard** : **Directive 93/42/EEC as amended 2007/47/EC**

This certificate refers to the information examined and read with manufacturer's declaration of conformity.  
Further, the product liability rests with the manufacturer or his representative in accordance with the council  
directive 93/42/EEC as amended 2007/47/EC. The CE Mark as shown below can be used, under the  
responsibility of manufacturer, after completion of a CE Declaration of conformity and compliance with the  
relevant CE Directives.

Certificate No.: **SPC17C1228**      Date of Initial Registration: 29-04-2017  
Date of This Certificate: 01-06-2020  
Surveillance audit on or before: 28-04-2021  
Date of Re-Certification: 29-04-2023

*[Signature]*  
Authorised Signatory  
**SP Certification Limited**  
130, Old Street, London,  
EC1V9BD, U.K.  
Email: info@spcertification.co.uk  
www.spcertification.co.uk

Accredited by Accreditation Forum of International Standards [AFIST (UK) LTD.]  
9, Park View Road, Leeds, LS4 2LG, United Kingdom (UK), Email : info@afist.org, Website : www.afist.org  
The approval is subject to the company maintaining its systems to the required standards, which will be monitored by SPC.  
The Certificate remains the property of SPC and must be returned on request.  
To check validity of this certificate please visit [www.spcertification.co.uk](http://www.spcertification.co.uk) and [www.afist.org](http://www.afist.org)

**Central Drugs Standard Control Organisation**  
**Directorate General of Health Services**  
**Ministry of Health & Family Welfare**  
**(Medical Device & Diagnostic Division)**

FDA Bhawan, Kotla Road  
New Delhi-110002  
Phone No-011-23236965  
Fax: 23236973  
Dated : 22-APR-2020

**File No. : NZ/MD/2019/000033**

**M/s Austeofix Surgical Pvt. Ltd.,**  
**10-11-12, PLOT NO. 6, Vivekanand Marg,**  
**C-Scheme, Jaipur, Rajasthan, India, 302001**  
**Jaipur, Jaipur, Rajasthan (India) - 302001**  
**Telephone No.: 9314522429 FAX:**  
**9782002006 Email: info@austeofix.com**

**Sub- Licence to manufacture for Sale or for Distribution of Class C or Class D medical devices in**  
**Sir, Form MD-9 under Medical Device Rules, 2017- regarding.**

Manufacturing licence No. MFG/MD/2020/000091 in Form MD-9 is hereby forwarded to you.  
This licence is subject to following conditions:

- Licence shall be produced when requested by the Medical Device Officer or any other senior officer under the control of Central Licensing Authority.
- The licence holder shall inform the Central Licensing Authority of the occurrence of any suspected unexpected serious adverse event and action taken thereon including any recall within fifteen days of such event coming to the notice of licence holder
- The licence holder shall obtain prior approval from the Central Licensing Authority, before any major change as specified in the Sixth Schedule is carried out and the Central Licensing Authority shall indicate its approval or rejection within forty five days and in case where no communication is received within the stipulated time from such Authority, such change shall be deemed to have been approved
- The licence holder shall inform any minor change as specified in the Sixth Schedule to the Central Licensing Authority within a period of thirty days after such minor change take place
- The licence holder shall carry out test of each batch of product manufactured prior to its release for compliance with specifications either in his own laboratory or in any other laboratory registered under sub-rule (3) of rule 83;



**Factory Address :-**

Plot No.81, Solitaire Industrial Park Phase 1, Dahmi Kalan. Jaipur Ajmer Exp. Highway

RIICO Ind.Area, Bagru, jaipur

Ph. : +91-9511348306

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