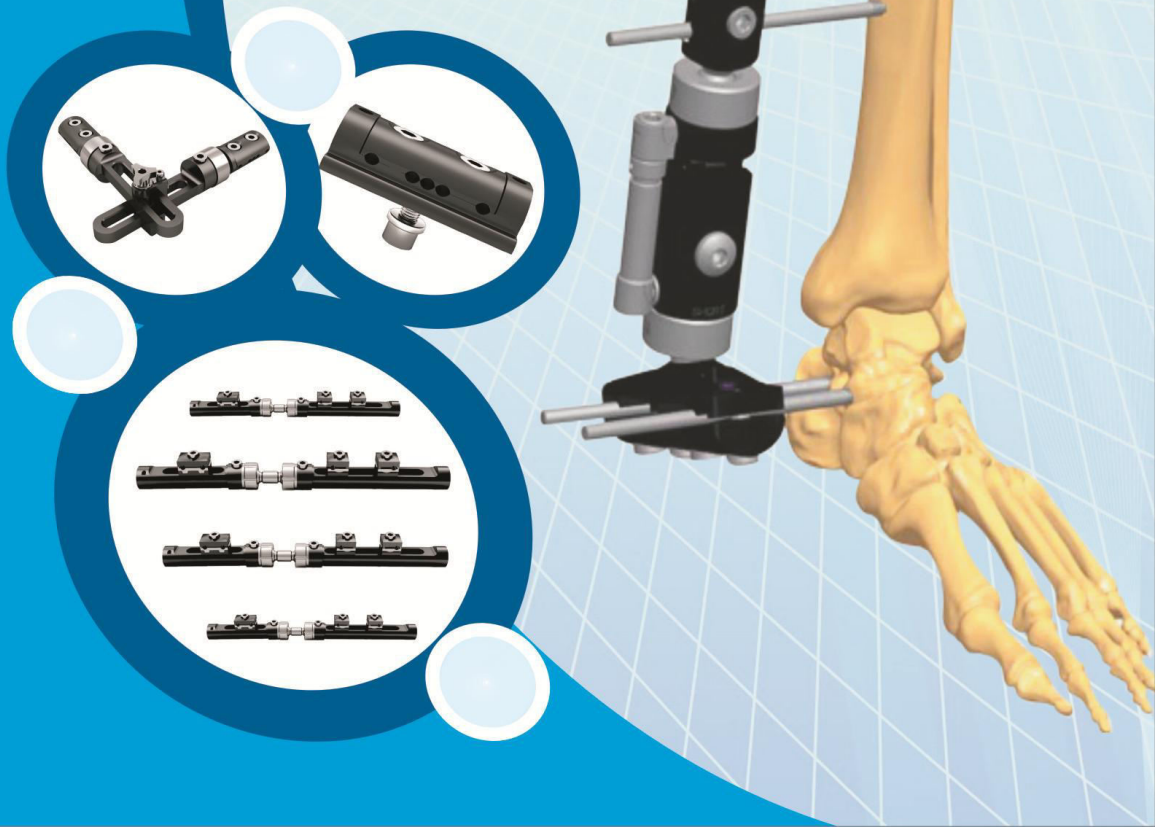
INDIAN FDA APPROVED

Austeofix™

Austeofix Surgical Pvt. Ltd.

A Perfect Fixation

AN ISO 9001:2015, ISO 13485:2016, CE & GMP CERTIFIED COMPANY



Rail Fixation System

Cat. AFR
RAIL
Size: 240mm, 300mm, 400 mm

Cat. AFEC
END CLAMP

Cat. AFCC
CENTRE CLAMP

Cat. AFSC
SWIVEL CLAMP

Cat. AFCD
C. D. UNIT
Size : 40mm, 80mm

Cat. AFTC
T- CLAMP

Rail Fixation System

Cat. AFTBS
T - BALL & SOCKET CLAMP

Cat. AFBSC
BALL & SOCKET CLAMP STANDARD

Cat. AFSP
SANDWICH PLATE

Cat. AFDRC
DYNA RING CLAMP

Cat. AFAK
ALLENKEY
Size : 6 MM ADULT

Cat. AFGSC
GRADUATED SWIVEL CLAMP

Cat. AFTEC
TEMPLATE END CLAMP

Rail Fixation System

Cat. AFTSC
TEMPLATE SWIVEL CLAMP

Cat. AFDS
DRILL SLEEVES
Size : 3.2mm, 4.5mm, 6.0mm

Cat. AFDWF
DYNAMIC WRIST FIXATOR

Cat. AFEC
ELBOW CLAMP

Cat. AFSAC
SELF ADJUSTING CLAMP

Cat. AFDEFL/M
DYNAMIC ORTHO FIXATOR

Cat. AFDEFS
ORTHO FIXATOR

Pediatric Rail Fixator

Cat. AFPR
PEDIATRIC RAIL
150MM, 200MM, 250MM

Cat. AFPCC
PEADIATRIC CENTRAL CLAMP

Cat. AFPEC
PEDIATRIC END CLAMP

Cat. AFPSC
PEDIATRIC SWIVEL CLAMP

Cat. AFPCDU
PEDIATRIC C D UNIT

Cat. DRILL SLEEVE
Size : 2.7 & 4.5 MM

Cat. AFAK
ALLENKEY
Size : 5 MM ADULT

Austeofix®

QUALITY MANAGEMENT SYSTEM

Certificate of Registration

ROHS

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 : **20DQGU58**
Initial Registration Date : 02/06/2020 Issuance Date : 02/06/2020
Date of Expiry* : 01/06/2021
Date of Re certification : 02/06/2023

DIRECTOR

IAF MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT

eiaC Emirates International Accreditation Centre 035-CB-QMS

ROHS Certification Pvt. Ltd.
408, Madhuban Building, 55 Nehru Place, New Delhi - 110 019, India
phone : +91.11.41525522 | e-mail : info@rohscertification.co.in | website : www.rohscertification.co.in
The Registration is not a Product Quality Certificate. "Subject to successful completion of surveillance audits.Visit for verification on: www.rohscertification.co.in
Certificate is the property of ROHS and return when demanded.

CERTIFICATE

SPC

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, ARTHOPLASTY, 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

Authorised Signatory

SP Certification Limited
130, Old Street, London,
EC1V9BD, U.K.
Email: info@spcertification.co.uk
www.spcertification.co.uk

CERTIFIED ISO 13485:2016 COMPANY

AFIST

SPC

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 system 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** and **www.afist.org**

CERTIFICATE

SPC

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

Authorised Signatory

SP Certification Limited
130, Old Street, London,
EC1V9BD, U.K.
Email: info@spcertification.co.uk
www.spcertification.co.uk

CE AFIST SPC

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 system 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** and **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 Form MD-9 under Medical Device Rules, 2017- regarding.

Sir,

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

1. Licence shall be produced when requested by the Medical Device Officer or any other senior officer under the control of Central Licensing Authority.
2. 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
3. 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
4. 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
5. 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
info@austeofix.com, www.austeofix.com