



CERTIFICATE

Of Compliance

This is to certify that the technical documentation has been independently assessed and compliant with the requirements of Medical Device Regulation (EU) 2017/745 (earlier legislation Council 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 : Medical Device Regulation (EU) 2017/745 (earlier legislation Council Directive 93/42/EEC)

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 Medical Device Regulation (EU) 2017/745 (earlier legislation Council Directive 93/42/EEC). 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: 06-07-2024
Surveillance audit on or before: 28-04-2025
Date of Recertification: 29-04-2026

Authorised Signatory

SP Certification Limited

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Accredited by Accreditation Forum of International Standards [AFIST (UK) LTD.]

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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

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