



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that:

Auxein Medical Private Limited Plot No. 168,169,170, Phase IV Sector 57, Kundli Industrial Area Sonipat HSIIDC Sonipat 131 028 Haryana India

Holds Certificate No:

MD 701953

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The Design, Development and Manufacture of Sterile & Non-Sterile Orthopaedic Implants, External Fixators, Orthopaedic Instruments, Spinal Implants, Cranio Maxillofacial Implants, Customized Implants & Arthroscopy Implants.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2018-12-23 Latest Revision Date: 2024-12-02



Effective Date: 2024-12-23 Expiry Date: 2027-12-22

Page: 1 of 2

...making excellence a habit."

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract. An electronic certificate can be authenticated <u>online</u>.

Printed copies can be validated at www.bsi-global.com/ClientDirectory or telephone +91 11 2692 9000.

Further clarifications regarding the scope of this certificate and the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization. This certificate is valid only if provided original copies are in complete set.

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000 BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK. A Member of the BSI Group of Companies.

Certificate No: MD 701953

Location

India

Auxein Medical Private Limited Plot No. 168,169,170, Phase IV Sector 57, Kundli Industrial Area Sonipat HSIIDC Sonipat 131 028 Haryana India Auxien Medical Private Limited Unit 2 HSIIDC, Plot No. 157 Phase V, Kundli Industrial Area Sector 56 Sonipat 131 028 Haryana Registered Activities

Design, Development and Manufacture of Sterile & Non-Sterile Orthopaedic Implants, External Fixators, Orthopaedic Instruments, Spinal Implants, Cranio Maxillofacial Implants, Customized Implants & Arthroscopy Implants.

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