



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 Medical Devices

Original Registration Date: 2018-12-23

Latest Revision Date: 2022-05-27

Effective Date: 2021-12-23

Expiry Date: 2024-12-22

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...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 online.

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.