



## 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 Haryana 131 028 India

Facility ID Number: F004411

Holds Certificate No: MDSAP 720782

The company listed on this certificate has been audited to and found to conform with ISO 13485:2016 including the following country specific requirements:

**USA:** 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D

Design, development and manufacture of sterile & non-sterile orthopaedic implants, maxilofacial, spinal implant, arthroscopy, external fixators, orthopaedic instruments and customised implants.

For and on behalf of BSI:

Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2020-05-06 Effective Date: 2024-12-23 Expiry Date: 2027-12-22

Page: 1 of 2

BSI Group America Inc. is an MDSAP recognised auditing organization

...making excellence a habit."

Certificate No: **MDSAP 720782** 

## Location Registered Activities

Auxein Medical Private Limited Plot No. 168,169,170, Phase IV Sector 57, Kundli Industrial Area

Sonipat HSIIDC

Sonipat Haryana

131 028 India

Facility ID Number: F004411

Auxien Medical Private Limited Unit 2

HSIIDC, Plot No. 157

Phase V, Kundli Industrial Area

Sector 56 Sonipat Haryana 131 028 India

Facility ID Number: F004411

Design, Development and Manufacture of sterile & non-sterile orthopaedic implants, External Fixators, Orthopaedic Instruments, Spinal Implants, Cranio Maxillofacial implants, customized implants & arthroscopy implants.

Manufacture of sterile & non-sterile orthopaedic implants, External Fixators, Orthopaedic Instruments, Spinal Implants, Cranio Maxillofacial implants, customized implants & arthroscopy implants.



Original Registration Date: 2020-05-06 Effective Date: 2024-12-23 Expiry Date: 2027-12-22

Page: 2 of 2