

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:

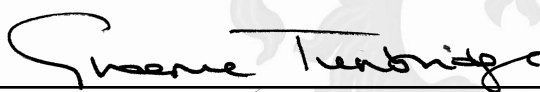
Australia: Therapeutic Goods (Medical Devices) Regulations, 2002, Schedule 3 Part 1 (excluding Part 1.6) - Full Quality Assurance Procedure

Brazil: RDC ANVISA n. 67/2009, RDC ANVISA n. 665/2022 - Good Manufacturing Practices, RDC ANVISA n. 551/2021

USA: 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 - Subparts A to D, 21 CFR 821

Design, development and manufacture of sterile & non-sterile orthopaedic implants, maxillofacial, 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: 2026-08-11

Expiry Date: 2027-12-22



BSI Group America Inc. is an MDSAP recognised auditing organization

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Location

Auxien 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

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.

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

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

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This certificate remains the property of BSI and shall be returned immediately upon request.

An electronic certificate can be authenticated [online](https://www.bsigroup.com/ClientDirectory). Printed copies can be validated at www.bsigroup.com/ClientDirectory

To be read in conjunction with the scope above or the attached appendix.