

# Certificate of Registration

## QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: **BIO CONCEPT CO., LTD.**  
No.1019, Liaohe Rd.  
Xinbei District  
Changzhou  
Jiangsu  
213000  
China

Facility ID Number: F007768

Holds Certificate No: **MDSAP 818101**

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

**Canada:** Medical Devices Regulations - Part 1 - SOR 98/282

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

Design and Development, Manufacture and Distribution of Dental Implants, Dental Implant Attachments, Dental Implantation Drills, Dental Implantation Instruments, Impression Taking System.

For and on behalf of BSI:

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Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

Original Registration Date: 2025-02-11

Effective Date: 2025-02-11

Expiry Date: 2028-02-10



BSI Group America Inc. is an MDSAP recognised auditing organization

Page: 1 of 1

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