

Certificate

Certificate No.: MD 2110610-1

Manufacturer: **BIO CONCEPT CO., LTD.**
Unit C, No. 26,
Huashan Middle Road, Xinbei Zone,
Changzhou,
213022 Jiangsu
P.R. China

REPs Facility ID: F003719

Certification criteria: ISO 13485:2016

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

United States 21 CFR 820, 21 CFR 803, 21 CFR 806, 21 CFR 807 –
Subparts A to D

Scope: Design and Development, Manufacture and Distribution of Dental
Implants, Dental Implant Attachments, Dental Implantation Drills,
Dental Implantation Instruments, Impression Taking System, Dental
Surgery Devices, Saw Blades, Drill Bits

TUV Rheinland of North America, Inc., an MDSAP recognized Auditing Organization, certifies that the quality management system of the Manufacturer has been audited against and found to conform the Certification criteria for the Scope contained in this certificate. The quality management system is subject to annual surveillance audit(s).

Project No.: 244381039-200

Issue Date: 2022-04-25

Effective Date: 2022-04-25

Expiry Date: 2025-02-22



Certification officer: Samuel Qin
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified on https://www.certipedia.com/quality_marks/9000014909?locale=en
or calling 1-888-743-4652.