

BIO CONCEPT Co., Ltd.
Unit C, No. 26, Huashan Middle Road,
Xinbei Zone, Changzhou,
213022 Jiangsu,
China

Email : medical-pro-
ducts@de.tuv.com

April 08, 2020

Re: Successful certification
Requirement: ISO 13485:2016 under MDSAP
Certificate number: MD 423639 154369823-30

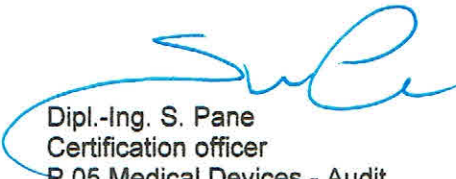
Dear Madam or Sir,

Thank you for your patience and kind support during the certification process. Please find enclosed the certificate stating compliance to the above-mentioned requirement.

As certification holder / MDSAP participant, your organization is subject to the following guideline: General Conditions for Promoting Certification and Using Certification Body/Auditing Organization Trade Marks and Accreditation Marks, found on the TÜV Rheinland website: https://www.tuv.com/en/usa/legal_disclaimer/imprint.html#tab4.

Please do not hesitate to contact us if you have any further questions or concerns.

Best regards,


Dipl.-Ing. S. Pane
Certification officer
P.05 Medical Devices - Audit

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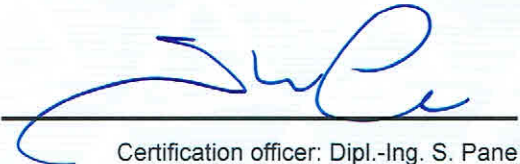
Certificate

Certificate No.: MD 423639 154369823-30
Manufacturer: **BIO CONCEPT Co., Ltd.**
Unit C, No. 26, Huashan Middle Road, Xinbei Zone, Changzhou,
213022 Jiangsu, China
D-U-N-S No.: 52-760-3266
Certification criteria ISO 13485:2016
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 Systems, 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.: 15096262 002
Issue Date: 2020-04-08
Effective Date: 2020-04-08
Expiry Date: 2022-02-22



Certification officer: Dipl.-Ing. S. Pane
TUV Rheinland of North America, Inc.

The validity of the certificate can be verified by calling 1-888-743-4652.