

# Certificate

**Quality Management System**  
**EN ISO 13485:2016**

Registration No.: SX 2110610-1

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

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, Drill Bits

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices. Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 15061954 013  
Effective date: 2022-06-06  
Expiry date: 2024-10-09  
Issue date: 2022-06-06



FUXIU Sheng  
Zertifizierungsstelle

TÜV Rheinland LGA Products GmbH  
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH • 51105 Köln

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

Contact

Tel. +49 911 655-5225

Mail: [service@de.tuv.com](mailto:service@de.tuv.com)

Date June 09, 2022

**Application for: QMS**

Certificate No.: SX 2110610-1

Requirement : EN ISO 13485:2016

Dear Madame or Sir

Enclosed please find the new certificate No. SX 2110610-1 replacing the previous certificate.

With effective date of the new certificate, the previous certificate becomes invalid.

Best regards,



Fuxiu Sheng  
Certification body

TÜV Rheinland  
LGA Products GmbH

Am Grauen Stein  
51105 Köln  
Germany

Headquarter

Tillystraße 2  
90431 Nuremberg

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Board of Management

Dipl.-Ing.  
Jörg Mähler, Spokesman

Dipl.-Kfm.  
Dr. Jörg Schlösser

Nuremberg HRB 26013  
VAT No.: DE 811835490

Chairman of the  
Supervisory Board

Dipl.-Ing. Ralf Scheller



TÜVRheinland®

**EC Certificate**  
**Directive 93/42/EEC Annex II, excluding Section 4**  
**Full Quality Assurance System**  
**Medical Devices**

**Registration No.:** HD 60133871 0001

**Report No.:** 15061954 008

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

**Products:** Dental Implants, Dental Implant Attachments, Dental  
Implantation Drills, Saw Blades, Drill Bits  
  
Replaces Approval, Registration No.: HD 60111041 0001

**Expiry Date:** 2023-10-09

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

**Effective Date:** 2018-12-18

**Date:** 2018-12-18

Notified Body



**TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg**  
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC  
concerning medical devices with the identification number 0197.

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Date June 09, 2022

**Application for: Vollst. QMS Annex II MDD**

Certificate No.: HD 60133871 0001

Requirement : Richtlinie 93/42/EWG

Dear Madame or Sir,

A surveillance audit of your quality management system was performed.

The audit team confirmed that your quality management system is applied effectively with respect to the above-mentioned requirement.

The sampled technical Documentation BKT-CE-SB, 2021-01-04/ Rev. 02 for the product Saw Blades of the product group MD 0106 Non-active instruments has been reviewed and in this configuration was found not to be in accordance with the above-mentioned requirement. Due to the negative result, the product Saw Blades should be restricted in the certificate

The recommendation of auditor is indicated in report no. 15061954 014

This letter confirms that the above-mentioned certificate will be restricted for the product Saw Blades.

Best regards,



Fuxiu Sheng  
Certification body

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LGA Products GmbH

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