

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



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.

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization
BIO CONCEPT CO., LTD.
Unit C, No. 26, Huashan Middle Road
Xinbei Zone
Changzhou
213022 Jiangsu
China

has established and applies a quality management system for medical devices
for the following scope:

**Design/development, Manufacture and Distribution of
Medical Devices
(see attachment for products included)**

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date: 2018-12-18
Certificate Registration No.: SX 60133872 0001
An audit was performed. Report No.: 15061954 008
This Certificate is valid until: 2021-10-09

Certification Body



Date 2018-12-18



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TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

**Attachment to
Certificate**

Registration No.: SX 60133872 0001
Report No.: 15061954 008

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

Scope:

Products:

Dental Implants, Dental Implant Attachments, Dental
Implantation Drills, Dental Implantation Instruments,
Impression Taking Systems, Dental Surgery Devices,
Saw Blades, Drill Bits

Certification Body



Date: 2018-12-18

