

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

Registration No.: HD 60111041 0001

Report No.: 15061954 005

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, Orthodontic Brackets, Orthodontic Bands, Orthodontic Buccal Tubes, Saw Blades, Drill Bits

Replaces Approval, Registration No.: HD 60087937 0001

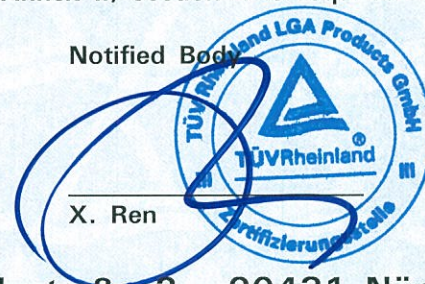
Expiry Date: 2018-10-09

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: 2016-09-07

Date: 2016-09-07

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.