

Declaration of Conformity

- 1. Manufacturer:** Hangzhou Xingchen 3B Dental Instrument & Material Co., Ltd.
Address: Building 1, No. 39 Kangxian Road, Gongshu District, 310015 Hangzhou, China
Tel: 0086 571 87655303
E-mail: hz3b.n1@hz3b.com
- 2. EU Representative:** Shanghai International Holding Corp. GmbH (Europe)
Address: Eiffestrasse 80, 20537 Hamburg, Germany
Tel: 0049-40-2513 175 Fax: 0049-40-255726
E-mail: shholding@hotmail.com
- 3. Name of product:**

Crimpable hooks	(UMDNS CODE: 15225)
Orthodontic brackets	(UMDNS CODE: 16360)
Orthodontic tubes	(UMDNS CODE: 16199)
Orthodontic bands	(UMDNS CODE: 16198)
Lingual buttons	(UMDNS CODE: 12035)

Classification: Class II a
Conformity assessment routine: MDD Annex V.3

We herewith declare that the above mentioned products meet the transposition into national law, the provisions of the following EC Council Directives and Standards. All supporting documentations are retained under the premises of the manufacturer.

DIRECTIVES

General applicable directives:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices (MDD 93/42/EEC). Amended by DIRECTIVE 2007/47/EC of 5 September 2007

4. Notified Body:

TÜV SÜD Product Service GmbH, Ridlerstraße 65, 80339 München, Germany

NB Identification number: 0123

(EC) Certificate(s): No. G2 15 08 74269 005

Expire date of the Certificate: 2020-11-17

Start of CE Marking: September, 2015

Place, Date of Issue: 2015-11-18

Signature: _____

Name: **Mr. Ni Qijun**

Position: **General Manager**

