

# Declaration of conformity

## 1. Name of manufacturer:

**Hangzhou JET Medical Equipment Co., Ltd.**

Add: No.71, Shanghai Bridge, Xinggongtang Village, Liangzhu Street, Yuhang District, Hangzhou, China

Postal code: 311112

Tel: 0086-571-86172207

Fax: 0086-571-88757679

Website: [www.hzjett.com](http://www.hzjett.com)

## 2. European Community Representative:

Name: **Wellkang Ltd**

Address: Suite B, 29 Harley Street

LONDON W1G 9QR, England, United Kingdom

Tel: +44 (20)30869438, 32876300

Fax: +44(20)76811874

E-mail: [AuthRep@CE-marking.eu](mailto:AuthRep@CE-marking.eu)

## 3. Name of product:

Orthodontic brackets (UMDNS CODE: 16360)

**Classification:** Class II a

**Conformity assessment routine:** MDD Annex V.3

The products above mentioned had been classified as Class II a, in accordance with Rules 5 of Annex IX of the MDD93/42/EEC.

We hereby declare that the above-mentioned products meet the provisions of the following EC Council Directive and Standards of 14 June 1993 (MDD/93/42/EEC). The products meet prospective uses and all supporting documentation are retained under the premise of manufacturer and the notified body.

We have appointed **SGS** Product Service act as our Notified Body to audit us in accordance with MDD 92/42/EEC Annex V.3

### Directives

#### General Applicable Directive:

**Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical device (MDD/93/42/EEC)**

**Standards: all applicable harmonized standards list.**

**4. Notified Body and Code: SGS United Kingdom Ltd, 202B World Parkway, Weston-super-Mare, BS22 6WA UK, Tel:+44(0)1934522917 Fax:+44(0)1934522137, [www.sgs.com](http://www.sgs.com)**

**Notified Body: 0120**

**EC Certificate No: CN15/20447**

**Signature:** 

**Name: Wang Guangliang**

**Position: General Manager**

**Date: 22, August, 2016**

