

# Declaration of conformity

## 1. Name of manufacturer:

**Hangzhou ORJ Medical Instrument & Material Co., Ltd.**

Add: No.8, Xiyuan 5<sup>th</sup> Rd., West Lake Tech. & Eco. District (SanDun),

Hangzhou, P.R.China

Postal code: 310030

Tel: 0086-571-88185501

Fax: 0086-571-88185503

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

## 2. European Community Representative:

Name: 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](mailto:shholding@hotmail.com)

## 3. Name of product:

Crimpable hooks (UMDNS CODE: 15225)

(F201-02/F201-08/F201-09/F201-06/F201-10/F201-11/F201-03/F201-12/F201-13/F201-04L/F201-04R/F201-15L/F201-15R/F202-02/F202-06/F202-07)

Orthodontic brackets (UMDNS CODE: 16360)

(TV21-40\*\*/TV21-41\*\*/TV21-44/TV22-40\*\*/TV22-41\*\*/TV22-44/TZ21-40\*\*/TZ21-41\*\*/TZ21-40/TZ21-44/TZ22-40\*\*/TZ22-41\*\*/TZ22-44/TZ32-40\*\*/TZ31-40\*\*/TZ32-41\*\*/TZ32-44/TB21-20\*\*/TB21-21\*\*/TB21-24/TB22-20\*\*/TB22-21\*\*/TB22-24/TB32-24/TB73-24J7/TB73-24/TB71-2111/TB71-2113/TB72-2114/TB71-2131/TB71-2133/ TD32-44/TA22-14/TB21-23/TB21-24/TB22-24/TB31-23/TB31-24/TB32-24/)

Orthodontic tubes (UMDNS CODE: 16199)

(J622-5105/J621-5105/J632-5105/J732-5105/J722-5105/J621-5115/J621-5125/J621-5135/J621-5145/J622-5115/J622-5125/J622-5135/J622-5145/J632-5115/J632-5125/J632-5135/J632-5145/J631-5115/J631-5125/J631-5135/J631-5145/J721-5115/J721-5125/J721-5135/J721-5145/J722-5115/J722-5125/J722-5135/J722-5145/J732-5115/J732-5125/J732-5135/J732-5145/J731-5115/J731-5125/J731-5135/J731-5145/J772-5111/J772-5121/J772-5131/J772-5141/J672-8111/J672-8121/J672-8131/J672-8141/J622-6221/J622-1111/J622-1121/J622-1131/J622-141/J622-2311/J622-2321/J622-2431/J622-2441/J612-6111/J622-1131)

Orthodontic bands (UMDNS CODE: 16198)

(D622-61S1/D622-61S1/D622-62S1/D622-62S2/D622-6311-\*/D622-6311-A1/D622-6311-A2/D622-6313-\*/D622-6313-A1/D622-6313-A2/D622-6321-\*/D622-6321-A1/D622-6321-A2/D622-6323-\*/D622-6323-A1/D622-6323-A2/D622-6431-\*/D622-6431-A1/D622-6431-A2/D622-6441-\*/D622-6441-A1/D622-6441-A2/D601-1-\*/D601-2-\*/D601-3-\*/D601-4-\*/D603-0/D622-5101/D622-5102/D622-6201/D622-6302/D622-6101/D606-S)

Lingual buttons/Sheath (UMDNS CODE: 12035)

(F302-02/F302-01/F321-02)

**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.

We have appointed TUV 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:** TUV Product Service GmbH, Ridlerstr.65, D-80339 Munich, Germany

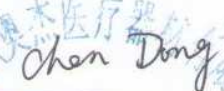
**Germany Certificate:** 0123

**EC Certificate No:** G2 13 07 58658 007

**Date CE certificate is expired:** 2018-08-26

**Date CE mark was affixed:** 2013-08-27

**Lot of the first products affixed CE mark:** B0810023

**Signature:**   
**Name:** Chen Dong  
**Position:** Production Manager  
**Date:** 9, JUNE, 2015

