Declaration of conformity

1. **Name of manufacturer:**

Hangzhou ORJ Medical Instrument & Material Co., Ltd.
Add: No.8, Xiyuan 5th 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 E-mail: yzhou@mmm.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

3. **Name of product:**

Positioning gauge---G110-01/G110-04/G110-03
Face Mask--- F511-01S/F511-02/F511-02S/F511-03/F511-04/F511-05
Orthodontic pliers---Q106-01/Q106-01L/Q106-01M/Q106-02/Q106-02L/Q106-05/ Q106-05M/Q106-05LM/Q106-06/Q106-06M/Q106-06L/Q106-06LM/ Q106-07/Q106-07L/Q106-08/Q106-08L/Q106-09/Q106-09L/Q106-10/ Q106-10L/Q107-01/Q107-02/Q105-01/Q105-02/Q105-03/Q105-16/Q105-04/ Q105-05/Q105-06/Q105-06L/Q105-07/Q105-07L/Q105-08/Q105-08L/Q105-09/ Q105-10/Q105-11/Q105-12/Q105-13/Q105-13L/Q105-14/Q105-15/Q103-01
Replacement tip --- Q301-01

Classification: **Class I**

Conformity assessment routine: MDD Annex Ⅴ.

The products above mentioned had been classified as Class I, in accordance with Rules 1 of Annex Ⅸ of the MDD 93/42/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 is retained under the premise of manufacturer.

Directives

General Applicable Directive:

Medical Device Directive: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical device (MDD 93/42/EEC: 2007)

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