



Product Service

# EC Certificate

## Production Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex V  
(Devices in Class IIa, IIb or III)

No. G2 13 07 58658 007

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

No. 8, XiYuan 5th Road  
West Lake Tech. & Eco. District (Sandun)  
310030 Hangzhou  
PEOPLE'S REPUBLIC OF CHINA

**EC-Representative:** Shanghai International Holding  
Corp. GmbH (Europe)

Eiffestraße 80  
20537 Hamburg  
GERMANY

**Product  
Category(ies):** Orthodontic Brackets,  
Orthodontic Tubes,  
Orthodontic Bands,  
Crimpable Hooks,  
Lingual Buttons

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex V. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class IIb and III devices an additional Annex III certificate is mandatory. See also notes overleaf.

**Report No.:** SH13438EXT01

**Valid from:** 2013-08-27

**Valid until:** 2018-08-26

Hans-Heiner Junker

**Date,** 2013-08-12



TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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**Facility(ies):**

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Ltd.  
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