



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

Page 1 of 2



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

Facility(ies):

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