



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 15 08 74269 005

Manufacturer:

**Hangzhou Xingchen 3B Dental
Instrument & Material Co., Ltd.**

Building 1, No. 39 Kangxian Road
Gongshu District

310015 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 Bands,
Orthodontic Buccal Tubes,
Sliding 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.:

SH15566EXT01

Valid from:

2015-11-18

Valid until:

2020-11-17

Date, 2015-11-03

Hans-Heiner Junker



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 15 08 74269 005**Facility(ies):**

Hangzhou Xingchen 3B Dental Instrument &
Material Co., Ltd.
Building 1, No. 39 Kangxian Road, Gongshu
District, 310015 Hangzhou, PEOPLE'S REPUBLIC
OF CHINA