

The management system of

# YAMAHACHI DENTAL MFG., CO.

Head Office 54-1 Ochigara, Nishiura-cho, Gamagori-city,  
Aichi-pref. Japan

has been assessed and certified as meeting the requirements of

## Directive 93/42/EEC on medical devices, Annex V

For the following products

**The scope of registration appears on page 2 of this certificate**

This certificate is valid from 10 January 2013 until 10 January 2018 and  
remains valid subject to satisfactory surveillance audits.  
Re certification audit due before 27 September 2015  
Issue 4. Certified since 12 August 2005

Certification is based on reports numbered JP/YOK/2687

This is a multi-site certification.  
Additional site details are listed on subsequent pages.

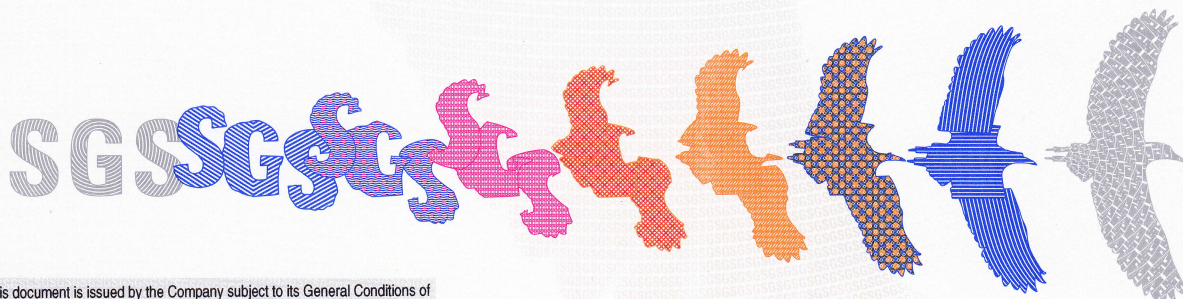
Authorised by

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# YAMAHACHI DENTAL MFG., CO.

## Directive 93/42/EEC on medical devices, Annex V

Issue 4

Detailed scope

**Dental gold-silver-palladium alloys**  
**Dental casting silver alloys**  
**Acrylic resin teeth**  
**Composite resin teeth**  
**Acrylic resin teeth (FX)**  
**Denture base polymers**  
**Dental acrylic resins for crown and bridge**  
**Dental root canal obturating points**  
**Dental absorbent points**

For placing on the market of Class IIb or Class III devices covered by this certificate, an EC Type Examination Certificate according to Annex III is required.

Additional facilities

**Katahara Factory**                    **56-10 Mitake, Katahara-cho, Gamagori-city,  
Aichi-pref. Japan**

**Kita Factory**                        **6 Miyashinden, Nishiura-cho, Gamagori-city,  
Aichi-pref. Japan**

**Yamahachi Dental Materials (Changshu) Co., Ltd.**  
**Zhitang Town, Changshu, Jiangsu Province, 215531, P.R. China**