EC Certificate Production Quality Assurance System: Certificate JP05/040221



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

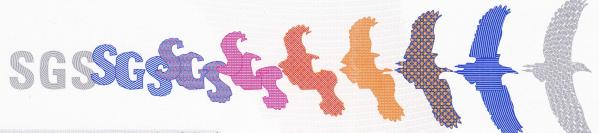
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# YAMAHACHI DENTAL MFG., CO.

### **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