

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.

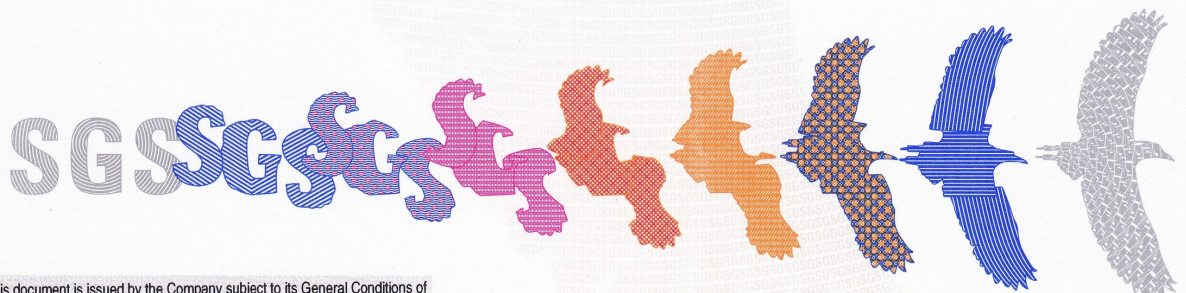
Authorised by

SGS United Kingdom Ltd, Notified Body 0120

202B Worle Parkway, Weston-super-Mare, BS22 6WA UK
t +44 (0)1934 522917 f +44 (0)1934 522137 www.sgs.com

SGS CE 13 0311

Page 1 of 2



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

