

EC Certificate Production Quality Assurance System: Certificate JP19/040512

The management system of

YAMAHACHI DENTAL MFG., CO.

Head Office

54-1 Ochigara, Nishiura-cho, Gamagori-city,
Aichi-pref., 443-0105 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 18 January 2021 until 24 May 2024
and remains valid subject to satisfactory surveillance audits.

Issue 3. Certified since 12 August 2005
and first certified by SGS Belgium NV since 12 November 2019

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



Pieter Weterings
Certification Manager

SGS Belgium NV, Notified Body 1639

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LPMD5008 - Certificate CE1639 Annex V_EN rev. 01

Page 1 of 2



YAMAHACHI DENTAL MFG., CO.

Directive 93/42/EEC

on medical devices, Annex V

Issue 3

Detailed scope

Acrylic resin teeth
Composite resin teeth
Acrylic resin teeth (FX)
Acrylic resin teeth (NS)
Denture base polymers
Dental acrylic resins for crown and bridge
Dental Disks and Blocks for prosthetic restoration

Where the above scope includes class IIb or class III medical device(s), a valid EC Type Examination Certificate according to Annex III is a mandatory requirement for each device in addition to this certificate to place that device on the market.

Additional facilities

Kita Factory

6 Miyashinden, Nishiura-cho, Gamagori-city,
Aichi-pref. , 443-0105 Japan

Yamahachi Dental
Materials (Changshu) Co.,
Ltd.

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