

The management system of

Huge Dental Material Co., LTD.

Shanghai Road (M), Rizhao City, Shangdong, P.R.China

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

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.

This certificate is valid from 9 February 2012 until 9 February 2017 and remains valid subject to satisfactory surveillance audits.
Re certification audit due before 14 November 2014
Issue 1. Certified since 9 February 2012

Certification is based on reports numbered CN/SHA 7799

Multiple certificates have been issued for this scope
The main certificate is numbered CN12/20077.00
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 M2

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Huge Dental Material Co., LTD.

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

Issue 1

Detailed scope

Synthetic polymer teeth

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

Huge Dental Material Co., LTD.

Unit 2-3F, No. 1295, Xinjinqiao Road, Pudong, Shanghai, P.R.China

EC Certificate Production Quality Assurance System: Certificate CN12/20077.01

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Shanghai Road (M), Rizhao City, Shangdong, P.R.China

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EC Certificate Production Quality Assurance System: Certificate CN12/20077.02

The management system of

Huge Dental Material Co., LTD.

Unit 2-3F, No. 1295, Xinqinqiao Road, Pudong, Shanghai, P. R. China

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