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By Royal Charter

EC Certificate - Production Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex V

No. **CE 01981**

Issued To: **Young Dental Manufacturing Co. 1, LLC**
Also Trading as Denticator, Biotrol,
Athena Champion, Young, Young Dental
and Young Dental Manufacturing
13705 Shoreline Court East
Earth City
Missouri
63045
USA

In respect of:

The manufacture of disposable dental prophy angles, brushes, cups, contra and right angle attachments, high and low speed dental handpieces and attachments.

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex V. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb and class III products an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):

Gary E Slack

Gary E Slack, Senior Vice President Medical Devices

First Issued: **1998-06-26** Date: **2020-09-11** Expiry Date: **2024-05-26**

...making excellence a habit.™

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Information and Contact: BSI, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Tel: + 31 20 346 0780
BSI Group The Netherlands B.V. registered in The Netherlands under 33264284.
A member of BSI Group of Companies.

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Supplementary Information to CE 01981

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NBOG Code(s)	Device Description	Intended Purpose as per IFU
Class IIa		
MD 1106	High Speed Dental Handpiece and attachments	N/A for Class IIa devices
MD 1106	Low Speed Dental Handpiece and attachments	N/A for Class IIa devices
MD 0401	Disposable Prophylaxis Angles	N/A for Class IIa devices
MD 0401	Cups	N/A for Class IIa devices
MD 0401	Brushes	N/A for Class IIa devices
MD 0401	Contra and Right Angle Attachments - Polisher	N/A for Class IIa devices

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List of Significant Subcontractors

Recognised as being involved in services relating to the product covered by:

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Subcontractor:	**Service(s) supplied**
Emergo Europe Prinsessegracht 20 2515 AP The Hague The Netherlands	**EU Representative**
Stoddard Manufacturing Co. Ltd Blackhorse Road, Letchworth Garden City, Hertfordshire, SG6 1HB United Kingdom	**Finished Device Supplier**

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EC Certificate - Production Quality Assurance Certificate History

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Date	Reference Number	Action
26 June 1998	-	First issue
31 March 2005	-	Reissue of Certificate in new format and expiry extension under CN/05/02
16 May 2005	-	Five year renewal, addition of Denticator International as trading name, extension of scope to include: contra and right angle attachments, aspiration /evacuation devices and cleaners
20 February 2009	7315540	Change to certificate to add "high and low speed dental hand pieces and attachments" reflecting the consolidation of CE 01838 on to CE 01981
08 July 2010	7521961	Certificate renewal Addition of subcontractor: "YI Europe Ltd" as EU Representative

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
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Date	Reference Number	Action
14 April 2015	8285226	Certificate Renewal. Change to certificate scope to remove " and cleaners". Removal of significant Subcontractor "Young Dental Manufacturing", 4401 Paredes Line Road, Brownsville. Texas, USA, 78521 for Manufacture Activity.
25 September 2016	8603003	Change EU Rep from Yi Europe, Limited, to Emergo Europe.
15 March 2019	7781696	Traceable to NB 0086.
25 February 2020	3072499	Removed Reusable Prophy Angles from certificate scope. Added device information table. Update to EU Rep address.
Current	3039766	Certificate Renewal. Removal of Aspiration and Evacuation Devices and Contra and Right Angle Attachments – Mandrels from scope. Addition of finished device supplier Stoddard Manufacturing Co. Ltd.

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
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