

EC Certificate - Production Quality Assurance

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

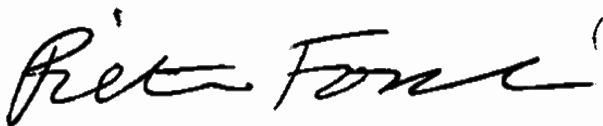
No. CE 01981
Issued To: **Young Dental Manufacturing Co. 1, LLC**
Also Trading as Denticator, Biotrol,
Athena Champion, Young, Young Dental
and Young Dental Manufacturing
13705 Shoreline Court East
Earth City
Missouri
63045
USA

In respect of:

The manufacture of dental prophylaxis angles, brushes, cups, contra and right angle attachments, aspiration/evacuation devices, 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 0086):



Pietro Foschi - Strategic Delivery Director

First Issued: **26 June 1998**

Date: **14 April 2015**

Expiry Date: **15 May 2020**

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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.

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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

YI Europe, Limited
Box 7037
S-187 11Täby
Sweden

EU Representative

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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

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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.

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