

DRAFT

Production Quality Assurance

No. CE 502907

Without a
hologram this
Certificate is
invalid

Issued to:

**B&L Biotech, Inc.
502, Gungjun tower
727-3, Gojan-dong
Danwon-gu
Ansan-si, Gyeonggi-do
425-906
South Korea**

In respect of:

The manufacture of Gutta percha heating systems and dental ultrasonic tips.

on the basis of our examination under the requirements of Council Directive 93/42/EEC, Annex V, Section 3.2.

For and on behalf of the British Standards Institution, a Notified Body for the above Directive (Notified Body Number 0086):

David Ford, Director, Healthcare and Testing Services

First Issued: **22 Dec 2005**

Date:

Expiration Date: **21 Dec 2010**

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Conditions of Approval

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive. 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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List of Significant Subcontractors

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

Certificate No. **CE 502907**

Date:

Issued to: **B&L Biotech, Inc.**
Ansan-si, Gyeonggi-do
South Korea

Subcontractor	Service(s) supplied
Emergo Europe Molenstraat 15 2513 BH The Hague Netherlands	EU Representative

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History of Quality Assurance Certificate

Certificate No: CE 502907
Issue Date:
Issued to: B&L Biotech, Inc.
Ansan-si, Gyeonggi-do
South Korea

Date	BSI Reference	Action
22 December 2005	-	First issue
13 October 2009	7373912	Change of name from 'B&L Biotech Co.' to 'B&L Biotech, Inc'. Scope to include 'dental porcelain and non-surgical ultrasonic tips'.
March 2010	7475138	Certificate Renewal. Company name change from B & L Biotech Co., Ltd to B & L Biotech, Inc. Scope changed from The Manufacture of gutta percha heating systems and non-surgical ultrasonic tips to The manufacture of Gutta percha heating systems and detail ultrasonic tips. Addition of subcontractor Emergo Europe, Molenstraat 15, 2513 BH, The Hague, The Netherlands.