

Certificate

Production Quality Assurance

No. CE 01488



Issued to:

GC Europe N.V.
Research Park
Interleuvenlaan 13
Leuven
B-3001
Belgium

In respect of:

The manufacture of dental glass ionomer restorative systems, luting cements, temporary filling, crown and bridge materials, conditioners, coating agents, composite resin and adhesive systems for direct and indirect restorations, temporary crown and bridge material, relining and periodontal dressing materials, ceramics and dental adhesives.

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: 17 Dec 1996

Date: 7 May 2009

Expiration Date: 6 May 2014

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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:

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Leuven
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Subcontractor

Service(s) supplied

GC America Inc
127th Street
Alsip
Illinois
USA
60803

Manufacture

GC Corporation
Hasunuma-Cho76-1
Itabashi-ku
Tokyo 174-8585
Japan

Manufacture

Klema Dentalprodukte GmbH
Koblacherstrasse 3a
A-6812 Meiningen
Austria

Manufacture

History of Quality Assurance Certificate

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Issue Date: 7 May 2009
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Date	BSI Reference Number	Action
17 December 1996	n/a	First Issue
04 February 1999	n/a	Scope Clarification
16 August 1999		Addition of Silicone resins
17 May 2004	4552894	Certificate five years renewal Scope amended to identify specific products Addition of GC America & GC Japan as Sub-contractors (clarification) New certificate format
24 January 2008	7061835	Scope clarification and addition of " Klema Dentalprodukte GmbH" as manufacturing sub contractor activity
07 May 2009	7296972	Certificate renewal