

EC Certificate - Production Quality Assurance

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

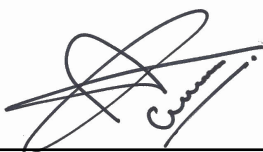
No. CE 01803
Issued To: **CMP Industries LLC**
also trading as Nobilium
also trading as Niranium
also trading as Ticonium
413 N. Pearl Street
Albany
New York
12207
USA

In respect of:

The manufacture of base metal casting alloys for crowns, bridges and partial dentures; base metal casting alloy accessories - hinges, latches, dental solders, dental clasp (wrought) wire and weld rods; and denture resin, liquids and powders and acrylic teeth.

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):



Albert Roossien, Regulatory Lead

First Issued: **1998-01-07**

Date: **2019-02-19**

Expiry Date: **2023-01-06**

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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.

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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List of Significant Subcontractors

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

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Subcontractor:	Service(s) supplied
Esschem Inc. 4000 Columbia Avenue PO 1139 Linwood PA 19061 USA	Manufacture
Huge Dental Material Co. Ltd Middle Shanhai Road Rizhao City Shandong 276800 China	Manufacture
Makevale Ltd. Valley House Marsh Lane Ware Hertfordshire SG12 9QP United Kingdom	Manufacture

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Subcontractor:

Service(s) supplied

Selection Importation Dentaire
5 Rue Paul Pousset
Les Ponts de Cé
49130
France

EU Representative

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EC Certificate - Production Quality Assurance Certificate History

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Date	Reference Number	Action
07 January 1998	-	First Issue.
19 June 1998	-	Adding "dental solders, dental clasp (wrought) wire" to the scope
23 December 2003	-	Five year renewal New certificate format.
21 December 2007	7137859	Certificate Renewal
25 November 2010	7519498	Scope Clarification by adding word 'for' Addition of three trading names Makevale Ltd., Herts UK & Esschem Inc. PA 19061, USA for Manufacturing. Selection Importation Dentaire S.A.R.L., France for EU Rep.
19 March 2013	7942744	Certificate renewal.
03 February 2017	8661719	Addition of acrylic teeth. Addition of Significant subcontractor; 'Huge Dental Material Co. Ltd, Middle Shanhai Road, Rizhao City, Shandong Province, 276800, P.R. China' for the activity Manufacture.

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Date	Reference Number	Action
12 March 2018	8788394	Certificate renewal. Change of EU Representative address from ` Selection Importation Dentaire S.A.R.L., Z.A. du Moulin Marcille, 5 Rue Paul Pousset, 49130 Les Pont-de-Ce, France` to `SELECTION IMPORTATION DENTAIRE, 5 Rue Paul Pousset, 49130 Les Ponts de Cé-France`.
Current	7780982	Traceable to NB 0086.

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