

EC Certificate - Production Quality Assurance

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

No.**CE 01488****Issued To:**

**GC Europe N.V.
Research Park
Interleuvenlaan 33
Leuven
B-3001
Belgium**

In respect of:

The manufacture of dental glass ionomer restorative systems, luting cements, fibre reinforcements, 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, alloys and adhesives for dental applications.

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):



Frank Lee, EMEA Compliance & Risk Director

First Issued: **17 December 1996**

Date: **29 September 2016**

Expiry Date: **06 May 2019**

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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.

EB sertifikatas - gamybos kokybės užtikrinimas

Direktyva 93/42 / EEB dėl medicinos prietaisų, V priedas

NR.

Išduota:

CE 01488**GC Europe N.V.
Research Park
Interleuvenlaan 33
Leuven
B-3001
Belgija**

Iš pagarbos:

Dantų stiklo jonometrų restauravimo sistemų, lydinio cemento, pluošto armatūros, laikinų užpildų, karūnų ir tiltų medžiagų, kondicionierių, dengimo medžiagų, kompozicinių dervų ir klijų sistemų, skirtų tiesioginėms ir netiesioginėms restauracijoms, laikinoms karūnoms ir tiltų medžiagoms, reliningoms ir periodontinėms tvarsliams, gamyba, keramika, lydiniai ir klijai dantų reikmėms.

remiantis kokybės užtikrinimo sistemos tyrimu pagal Tarybos direktyvos 93/42 / EEB V priedo reikalavimus. Kokybės užtikrinimo sistema atitinka direktyvos reikalavimus. IIb ir III klasių produktų pateikimui į rinką reikalingas III priedo sertifikatas.

BSI ir jos vardu notifikuotoji įstaiga dėl minėtos direktyvos (notifikuotosios įstaigos numeris 0086):

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