

UKCA Certificate - Production Quality Assurance

Part II of The Medical Devices Regulations 2002, Annex V [as modified by Part 2 of Schedule 2A to The Medical Devices Regulations 2002]

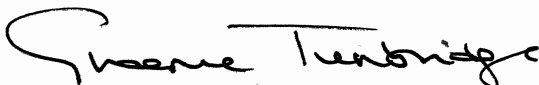
No. UKCA 778482
Issued To: GC Europe N.V.
Research Park
Interleuvenlaan 33
Leuven
B-3001
Belgium

In respect of:

The manufacture and final inspection of non-sterile 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 Part II of the Medical Devices Regulations 2002, Annex V [as modified by Part II of Schedule 2A to The Medical Devices Regulations 2002]. The quality assurance system meets the requirements of the regulation. For the placing on the market of class IIb and class III products an Annex III certificate (modified as described above) is required.

For and on behalf of BSI, an Approved Body for the above Regulation (Approved Body Number 0086):



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issued: **2023-04-27**

Date: **2024-10-09**

Expiry Date: **2029-05-06**

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Supplementary Information to UKCA 778482

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Device Code	Device Name	Intended purpose per IFU
Class IIa		
MD 0402	Dental resin and composite based luting cements	---
MD 0402	Glass ionomer based luting and restorative cements	---
MD 0402	Relining dental and periodontal dressing materials	---
MD 0402	Dental alloys for casting	---
MD 0402	Dental reinforcing fibers, composite restorative materials and root canal posts	---
MD 0402	Dental adhesive materials	---
MD 0402	Dental etching composites, glazing, hardening and restorative varnish materials	---
MD 0402	Temporary filling dental materials, cements and crown/bridge resins	---
MD 0402	Composite block for milling CAD/CAM indirect restorations	---

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Certificate History

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Date	Reference Number	Action
2023-04-27	3756860	First issue; Traceable to CE 01488
Current	30170001	Certificate renewal

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