



**EC DECLARATION OF CONFORMITY**  
**According to Annex V and Annex VII of MDD 93/42/EEC**

TF86 01      27 January 2015  
GMDN 16704

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

We ensure and declare under our sole responsibility that the product :

**GC FujiCEM 2**

to which this declaration relates, is in conformity with the following standards or other normative documents :

**ISO 4049: 2019 Dentistry - Polymer-based restorative materials**

**ISO 9917-2: 2010 Dentistry water-based cements – Part 2: Resin-modified cements**

**EN ISO 13485:2016 Medical Devices -Quality Management Systems-Requirements for Regulatory Purposes**

and meets the provisions of Council Directive 93/42/EEC concerning Medical Devices which apply to it, and is manufactured in accordance with the technical documentation.

This product is Class IIa according to rule 8 of annex IX of the Council Directive.

Notified Body: British Standards Institution (n°2797).



Leuven, .....09/03/2021.....  
Date

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Mario Minale  
Head of Regulatory Affairs  
On behalf of GC EUROPE N.V.

## LIST OF PRODUCTS

Article Code	New Article code	Description
900901	10003463	GC FujiCEM 2 starter kits – Metallic Paste pack dispenser
900900	10003462	GC FujiCem 2 starter kits – Plastic dispenser
900898	10003460	GC FujiCEM 2 SL, Automix Package
900897	10003459	GC FujiCEM 2 SL, Refill
004647	70000009	GC FujiCEM 2, Dispenser
001573	70000002	GC Paste Pak Dispenser
900903	10003465	GC FujiCEM 2 Mixing Tips SL for Endo, Refill Pack (10pcs) (only compatible with FujiCEM 2 SL cartridge)
900902	10003464	GC FujiCEM 2 Mixing Tips SL, Refill Pack, 20pcs (only compatible with FujiCEM 2 SL cartridge)
900915	10003470	GC FujiCem 2 SL Bulk Mixing Tips (100pcs)