



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

TF151

11 Febr 2019

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 Evolve

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

EN ISO 13485:2016	Medical devices -- Quality management systems - Requirements for regulatory purposes
ISO 9917-2:2017	Dentistry – Water-based cements – Part 2 : Resin-modified cement

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.....

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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
012950	10004928	GC FujiCEM Evolve Triple Pack Automix 3 x GC FujiCEM Evolve syringe (9.2 g / 5.0 ml)+ 45x GC Push and Click Tip Regular
012949	10004916	GC FujiCEM Evolve Triple Pack Handmix 3 x GC FujiCEM Evolve syringe (9.2 g / 5.0 ml)+ 1x Mixing Pad #22
013584	10006621	GC FujiCEM Evolve Clinic Pack 8x GC FujiCEM Evolve syringe (9.2 g / 5.0 ml) & 2x Mixing Pad #22
012948	10004926	GC FujiCEM Evolve Single Pack 1x GC FujiCEM Evolve syringe (9.2 g / 5.0 ml) & 15 x GC Push and Click Tip Regular
012953	10004930	GC FujiCEM Evolve Triple Pack Automix 3 x GC FujiCEM Evolve syringe (9.2 g / 5.0 ml)+ 45x GC Push and Click Tip Regular
012952	10004871	GC FujiCEM Evolve Triple Pack Handmix 3 x GC FujiCEM Evolve syringe (9.2 g / 5.0 ml)+ 1x Mixing Pad #22
012951	10004927	GC FujiCEM Evolve Single Pack 1x GC FujiCEM Evolve syringe (9.2 g / 5.0 ml) & 15 x GC Push and Click Tip Regular
901609	10004925	GC FujiCEM Evolve Triple pack + Mixing tips FujiCEM Evolve Triple Pack Handmix (3 syringes, 5.0 ml/9.2 g) Push and Click Tip Regular (x15) mixing tips
901610	10004832	GC FujiCEM Evolve Triple pack + Mixing tips FujiCEM Evolve Triple Pack Handmix (3 syringes, 5.0 ml/9.2 g) Push and Click Tip Regular (x15) mixing tips