



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

TF02 09 May 2006
GMDN 16704

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

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

GC Fuji PLUS
GC Fuji PLUS CAPSULE
GC Fuji PLUS EWT

to which this declaration relates are 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: 2010	Dentistry - Water-based cements – Part 2: Resin-modified cements

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

These products are Class IIa according to rule 8 of annex IX of the Council Directive.

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

Leuven, 25/05/2021.....
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
000219	10000084	Fuji Plus powder 15g
000220	10000085	Fuji Plus liquid 7ml
000222	10000087	GC Fuji PLUS, 50 Capsules, Yellow (Content: Box with 50 Capsules, with 0.36g Powder and 0.18g (0.16ml) Liquid each, Mixed Volume per Capsule 0.19ml)
000231	10000088	Fuji Plus EWT powder 15g A3
001409	10000157	GC Fuji PLUS, Intro Package, Full Set, A3 (Content: 15g Powder, 7ml Liquid, 6.5ml conditioner & Accessories)
001410	10000158	Fuji Plus powder Translucent 1
001411	10000159	Fuji Plus powder A3 15g
001418	10000161	Fuji Plus box of 50 caps A3 (Content: Box with 50 Capsules, with 0.36g Powder and 0.18g (0.16ml) Liquid each, Mixed Volume per Capsule 0.19ml)
003209	10000508	Fuji Plus box of 50 caps EEP (Content: Box with 50 Capsules, with 0.36g Powder and 0.18g (0.16ml) Liquid each, Mixed Volume per Capsule 0.19ml)
003210	10000509	Fuji Plus box of 50 caps A3 EE (Content: Box with 50 Capsules, with 0.36g Powder and 0.18g (0.16ml) Liquid each, Mixed Volume per Capsule 0.19ml)
003211	10000510	GC Fuji PLUS, Intro Package, Full Set, A3 EEP (Content: 15g Powder, 7ml Liquid, 6.5ml conditioner & Accessories)
003212	10000511	Fuji Plus powder Yellow 15g EE
003213	10000512	Fuji Plus powder A3 15g EEP
003214	10000513	Fuji Plus powder Translucent 1
003215	10000514	Fuji Plus liquid 7ml EEP
003231	10000521	Fuji Plus EWT powder 15g A3 EE
800126	10001808	GC Fuji Plus Capsule promo
901519	10003751	PROMO Fuji Plus Caps A3 + Freegenol WEP
901520	10003752	PROMO Fuji Plus Caps A3 + Freegenol EEP
900508	10003295	Fuji Plus Capsule A3 promo 50+10 EEP
900507	10003294	GC Fuji Plus Capsule promo 50+10 EEP
800127	10001809	Fuji Plus Capsule A3 promo