



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

TF01 01 16 Nov. 2007
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 II LC (Improved)
GC Fuji II LC CAPSULE

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: 2017 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,17/05/2021.....
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	
000138	10000034	GC Fuji II, LC Improved, 50 Capsules, A1	Box with 50 Capsules, 0.33g Powder and 0.10g (0.085ml) Liquid each, Mixed Volume per Capsule 0.10ml
000139	10000035	GC Fuji II, LC Improved, 50 Capsules, A2	Box with 50 Capsules, 0.33g Powder and 0.10g (0.085ml) Liquid each, Mixed Volume per Capsule 0.10ml
000140	10000036	GC Fuji II, LC Improved, 50 Capsules, A3	Box with 50 Capsules, 0.33g Powder and 0.10g (0.085ml) Liquid each, Mixed Volume per Capsule 0.10ml
000141	10000037	GC Fuji II, LC Improved, 50 Capsules, A3.5	Box with 50 Capsules, 0.33g Powder and 0.10g (0.085ml) Liquid each, Mixed Volume per Capsule 0.10ml
000142	10000038	GC Fuji II, LC Improved, 50 Capsules, A4	Box with 50 Capsules, 0.33g Powder and 0.10g (0.085ml) Liquid each, Mixed Volume per Capsule 0.10ml
000137	10000033	GC Fuji II, LC Improved, 50 Capsules, Assortment	Box with 50 Capsules (10 pcs. each of A4, B2, B3, C2, 5 pcs. each of B4, D2), 0.33g Powder and 0.10g (0.085ml) Liquid each, Mixed Volume per Capsule 0.10ml
000143	10000039	GC Fuji II, LC Improved, 50 Capsules, B2	Box with 50 Capsules, 0.33g Powder and 0.10g (0.085ml) Liquid each, Mixed Volume per Capsule 0.10ml
000144	10000040	GC Fuji II, LC Improved, 50 Capsules, B3	Box with 50 Capsules, 0.33g Powder and 0.10g (0.085ml) Liquid each, Mixed Volume per Capsule 0.10ml
000145	10000041	GC Fuji II, LC Improved, 50 Capsules, B4	Box with 50 Capsules, 0.33g Powder and 0.10g (0.085ml) Liquid each, Mixed Volume per Capsule 0.10ml
000146	10000042	GC Fuji II, LC Improved, 50 Capsules, C2	Box with 50 Capsules, 0.33g Powder and 0.10g (0.085ml) Liquid each, Mixed Volume per Capsule 0.10ml





000147	10000043	GC Fuji II, LC Improved, 50 Capsules, C4	Box with 50 Capsules, 0.33g Powder and 0.10g (0.085ml) Liquid each, Mixed Volume per Capsule 0.10ml
000148	10000044	GC Fuji II, LC Improved, 50 Capsules, D2	Box with 50 Capsules, 0.33g Powder and 0.10g (0.085ml) Liquid each, Mixed Volume per Capsule 0.10ml
900018	10003259	GC Fuji II, LC Improved, 3-2 Pack	3x 15g Powder: A2, A3, B3, 2x 8g/6.8ml Liquid
000195	10000062	GC Fuji II, LC Improved, 15g Powder, A1	/
000196	10000063	GC Fuji II, LC Improved, 15g Powder, A2	/
000197	10000064	GC Fuji II, LC Improved, 15g Powder, A3	/
000198	10000065	GC Fuji II, LC Improved, 15g Powder, A3.5	/
000199	10000066	GC Fuji II, LC Improved, 15g Powder, A4	/
000200	10000067	GC Fuji II, LC Improved, 15g Powder, B2	/
000201	10000068	GC Fuji II, LC Improved, 15g Powder, B3	/
000202	10000069	GC Fuji II, LC Improved, 15g Powder, B4	/
000203	10000070	GC Fuji II, LC Improved, 15g Powder, C2	/



000204	10000071	GC Fuji II, LC Improved, 15g Powder, C4	/
000205	10000072	GC Fuji II, LC Improved, 15g Powder, D2	/
000206	10000073	GC Fuji II, LC Improved, 6.8ml (8g) Liquid	/
003233	10000523	GC Fuji II, LC Improved, 50 Capsules, A1	Box with 50 Capsules, 0.33g Powder and 0.10g (0.085ml) Liquid each, Mixed Volume per Capsule 0.10ml
003234	10000524	GC Fuji II, LC Improved, 50 Capsules, A2	Box with 50 Capsules, 0.33g Powder and 0.10g (0.085ml) Liquid each, Mixed Volume per Capsule 0.10ml
003235	10000525	GC Fuji II, LC Improved, 50 Capsules, A3	Box with 50 Capsules, 0.33g Powder and 0.10g (0.085ml) Liquid each, Mixed Volume per Capsule 0.10ml
003236	10000526	GC Fuji II, LC Improved, 50 Capsules, A3.5	Box with 50 Capsules, 0.33g Powder and 0.10g (0.085ml) Liquid each, Mixed Volume per Capsule 0.10ml
003237	10000527	GC Fuji II, LC Improved, 50 Capsules, A4	Box with 50 Capsules, 0.33g Powder and 0.10g (0.085ml) Liquid each, Mixed Volume per Capsule 0.10ml
003244	10000534	GC Fuji II, LC Improved, 50 Capsules, Assortment	Box with 50 Capsules (10 pcs. each of A4, B2, B3, C2, 5 pcs. each of B4, D2), 0.33g Powder and 0.10g (0.085ml) Liquid each, Mixed Volume per Capsule 0.10ml
003238	10000528	GC Fuji II, LC Improved, 50 Capsules, B2	Box with 50 Capsules, 0.33g Powder and 0.10g (0.085ml) Liquid each, Mixed Volume per Capsule 0.10ml
003239	10000529	GC Fuji II, LC Improved, 50 Capsules, B3	Box with 50 Capsules, 0.33g Powder and 0.10g (0.085ml) Liquid each, Mixed Volume per Capsule 0.10ml
003240	10000530	GC Fuji II, LC Improved, 50	Box with 50 Capsules, 0.33g Powder and 0.10g (0.085ml) Liquid each, Mixed Volume per Capsule



		Capsules, B4	0.10ml
003241	10000531	GC Fuji II, LC Improved, 50 Capsules, C2	Box with 50 Capsules, 0.33g Powder and 0.10g (0.085ml) Liquid each, Mixed Volume per Capsule 0.10ml
003242	10000532	GC Fuji II, LC Improved, 50 Capsules, C4	Box with 50 Capsules, 0.33g Powder and 0.10g (0.085ml) Liquid each, Mixed Volume per Capsule 0.10ml
003243	10000533	GC Fuji II, LC Improved, 50 Capsules, D2	Box with 50 Capsules, 0.33g Powder and 0.10g (0.085ml) Liquid each, Mixed Volume per Capsule 0.10ml
900469	10003276	GC Fuji II, LC Improved, 3-2 Pack	3x 15g Powder: A2, A3, B3, 2x 8g/6.8ml Liquid
003252	10000542	GC Fuji II, LC Improved, 15g Powder, A1	/
003253	10000543	GC Fuji II, LC Improved, 15g Powder, A2	/
003254	10000544	GC Fuji II, LC Improved, 15g Powder, A3	/
003255	10000545	GC Fuji II, LC Improved, 15g Powder, A3.5	/
003256	10000546	GC Fuji II, LC Improved, 15g Powder, A4	/
003257	10000547	GC Fuji II, LC Improved, 15g Powder, B2	/
003258	10000548	GC Fuji II, LC Improved, 15g Powder, B3	/
003259	10000549	GC Fuji II, LC Improved, 15g	/





		Powder, B4	
003260	10000550	GC Fuji II, LC Improved, 15g Powder, C2	/
003261	10000551	GC Fuji II, LC Improved, 15g Powder, C4	/
003262	10000552	GC Fuji II, LC Improved, 15g Powder, D2	/
003263	10000553	GC Fuji II, LC Improved, 6.8ml (8g) Liquid	/
800143	10001811	GC Fuji II LC Capsules A3 Promo	/
800142	10001810	GC Fuji II LC Capsules A2 Promo	