



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

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

EN ISO 13485:2012 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 5 of annex IX of the Council Directive.

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

Leuven,12/04/2019.....
Date


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



LIST OF PRODUCTS

Article code	Description
000219	GC Fuji Plus powder 15g
000220	GC Fuji Plus liquid 7ml
000222	GC Fuji Plus box of 50 caps
001409	GC Fuji Plus Full Set A3
001410	GC Fuji Plus powder Translucent 15g
001411	GC Fuji Plus powder A3 15g
001418	GC Fuji Plus box of 50 caps A3
003209	GC Fuji Plus box of 50 caps EEP
003210	GC Fuji Plus box of 50 caps A3 EEP
003211	GC Fuji Plus Full Set A3 EEP
003212	GC Fuji Plus powder Yellow 15g EEP
003213	GC Fuji Plus powder A3 15g EEP
003214	GC Fuji Plus powder Translucent 15g EEP
003215	GC Fuji Plus liquid 7ml EEP
003231	GC Fuji PLUS, EWT, 15 g Powder, A3, EEP
800126	GC Fuji Plus Capsule promo
800127	GC Fuji Plus Capsule A3 promo
900507	GC Fuji Plus Capsule promo 50+10 EEP
900508	GC Fuji Plus Capsule A3 promo 50+10 EEP
901410	GC Fuji Plus Caps A3 - 20 pack