



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

TF03 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 I
GC Fuji I CAPSULE

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

ISO 9917-1:2007 – Dentistry Water-based cements,
Part I: Powder/liquid acid-base 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,12/05/2021.....
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
000134	10000030	GC Fuji I powder 35g
000135	10000031	GC Fuji I liquid 25g
000136	10000032	GC Fuji I 1-1 pkg
000240	10000091	GC Fuji Cap I box of 50 caps
003106	10000503	GC Fuji I Box of 50 caps EEP
003201	10000504	GC Fuji I 1-1 pkg EEP
003203	10000505	GC Fuji I powder 35g EEP
003205	10000506	GC Fuji I liquid 25g EEP