



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

TF08 09 Jan. 2009
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 IX GP
GC Fuji IX GP CAPSULE
GC Fuji IX GP FAST

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 1 : 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
000153	10000045	GC Fuji IX GP 1-1 pkg A3
000158	10000046	GC Fuji IX GP powder 15g A2
000159	10000047	GC Fuji IX GP powder 15g A3
000160	10000048	GC Fuji IX GP powder 15g A3.5
000161	10000049	GC Fuji IX GP powder 15g B2
000162	10000050	GC Fuji IX GP powder 15g B3
000163	10000051	GC Fuji IX GP powder 15g C4
000164	10000052	GC Fuji IX GP liquid 6,4ml
000166	10000053	GC Fuji IX GP box of 50 caps A2
000167	10000054	GC Fuji IX GP box of 50 caps A3
000168	10000055	GC Fuji IX GP box of 50 caps A3.5
000169	10000056	GC Fuji IX GP box of 50 caps B2
000170	10000057	GC Fuji IX GP box of 50 caps B3
000171	10000058	GC Fuji IX GP box of 50 caps C4
000212	10000078	GC Fuji IX GP Fast box of 50 caps A2
000213	10000079	GC Fuji IX GP Fast box of 50 caps A3
000214	10000080	GC Fuji IX GP Fast box of 50 caps A3.5
000215	10000081	GC Fuji IX GP Fast box of 50 caps B2
000216	10000082	GC Fuji IX GP Fast box of 50 caps B3
000217	10000083	GC Fuji IX GP Fast box of 50 caps C4
002022	10000324	GC Fuji IX GP Fast box of 50 caps A1
003264	10000554	GC Fuji IX GP 1-1 pkg A3 EEP
003265	10000555	GC Fuji IX GP powder 15g A2 EEP
003266	10000556	GC Fuji IX GP powder 15g A3 EEP
003267	10000557	GC Fuji IX GP powder 15g A3.5 EEP
003268	10000558	GC Fuji IX GP powder 15g B2 EEP
003269	10000559	GC Fuji IX GP powder 15g B3 EEP
003270	10000560	GC Fuji IX GP powder 15g C4 EEP
003271	10000561	GC Fuji IX GP liquid 6,4ml EEP
003273	10000563	GC Fuji IX GP box of 50 caps A2 EEP
003274	10000564	GC Fuji IX GP box of 50 caps A3 EEP
003275	10000565	GC Fuji IX GP box of 50 caps A3.5 EEP
003276	10000566	GC Fuji IX GP box of 50 caps B2 EEP
003277	10000567	GC Fuji IX GP box of 50 caps B3 EEP
003278	10000568	GC Fuji IX GP box of 50 caps C4 EEP
003288	10000578	GC Fuji IX GP Fast box of 50 caps A1 EEP
003289	10000579	GC Fuji IX GP Fast box of 50 caps A2 EEP
003290	10000580	GC Fuji IX GP Fast box of 50 caps A3 EEP
003291	10000581	GC Fuji IX GP Fast box of 50 caps A3.5 EEP
003292	10000582	GC Fuji IX GP Fast box of 50 caps B2 EEP
003293	10000583	GC Fuji IX GP Fast box of 50 caps B3 EEP
003294	10000584	GC Fuji IX GP Fast box of 50 caps C4 EEP





800002	10001768	GC Fuji IX GP 3-2 pkg
900444	10003272	GC Fuji IX GP 3-2 pkg EEP