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

TF08 26 Febr. 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 product :

GC Fuji IX GP EXTRA (Caps)

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

EN ISO 13485:2016 Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes

ISO 9917-1: 2007 Dentistry – Water-based cements – Part 1: Powder/liquid acid-base cements

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

This product is Class **IIa** according to rule 5 of annex IX of the Council Directive.

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

Leuven, ...24/4/2019.....
Date

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

LIST OF PRODUCTS

Article code	Description
002533	GC Fuji IX GP Extra box of 50 caps Assorted
002534	GC Fuji IX GP Extra box of 50 caps A1
002535	GC Fuji IX GP Extra box of 50 caps A2
002536	GC Fuji IX GP Extra box of 50 caps A3
002537	GC Fuji IX GP Extra box of 50 caps A3.5
002538	GC Fuji IX GP Extra box of 50 caps B1
002539	GC Fuji IX GP Extra box of 50 caps B2
002540	GC Fuji IX GP Extra box of 50 caps B3
002541	GC Fuji IX GP Extra box of 50 caps C4
003279	GC Fuji IX GP Extra box of 50 caps Ass. EEP
003280	GC Fuji IX GP Extra box of 50 caps A1 EEP
003281	GC Fuji IX GP Extra box of 50 caps A2 EEP
003282	GC Fuji IX GP Extra box of 50 caps A3 EEP
003283	GC Fuji IX GP Extra box of 50 caps A3.5 EEP
003284	GC Fuji IX GP Extra box of 50 caps B1 EEP
003285	GC Fuji IX GP Extra box of 50 caps B2 EEP
003286	GC Fuji IX GP Extra box of 50 caps B3 EEP
003287	GC Fuji IX GP Extra box of 50 caps C4 EEP
005072	GC Fuji IX GP EXTRA Liquid 8g
005073	GC Fuji IX GP EXTRA Liquid 8g EEP
005074	GC Fuji IX GP EXTRA 1-1 A2
005075	GC Fuji IX GP EXTRA 1-1 A3
005076	GC Fuji IX GP EXTRA 1-1 A2 EEP
005077	GC Fuji IX GP EXTRA 1-1 A3 EEP
005078	GC Fuji IX GP EXTRA Powder 15g A1
005079	GC Fuji IX GP EXTRA Powder 15g A2
005080	GC Fuji IX GP EXTRA Powder 15g A3
005081	GC Fuji IX GP EXTRA Powder 15g A3.5
005082	GC Fuji IX GP EXTRA Powder 15g B1
005083	GC Fuji IX GP EXTRA Powder 15g B2
005084	GC Fuji IX GP EXTRA Powder 15g B3
005085	GC Fuji IX GP EXTRA Powder 15g C4
005086	GC Fuji IX GP EXTRA Powder 15g A1 EEP
005087	GC Fuji IX GP EXTRA Powder 15g A2 EEP
005088	GC Fuji IX GP EXTRA Powder 15g A3 EEP
005089	GC Fuji IX GP EXTRA Powder 15g A3.5 EEP
005090	GC Fuji IX GP EXTRA Powder 15g B1 EEP
005091	GC Fuji IX GP EXTRA Powder 15g B2 EEP
005092	GC Fuji IX GP EXTRA Powder 15g B3 EEP
005093	GC Fuji IX GP EXTRA Powder 15g C4 EEP
900815	GC Fuji IX GP ExtraCaps A2 Promo
900816	GC Fuji IX GP ExtraCaps A3 Promo