



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

TF62 20 January 2011
GMDN 45294 (Coat)/ 16704 (Fil)

GC EUROPE N.V.
Research Park
Interleuvenlaan 33
B-3001 Leuven
Belgium

We ensure and declare under our sole responsibility that the product :

EQUIA
EQUIA Fil
EQUIA Coat

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

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 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	Description	
900555	10003305	GC EQUIA, Intro Pack, 50 Capsules, A2	50 Capsules EQUIA Fil (0.40g) Powder and 0.12g (0.10ml) Liquid, Mixed Volume per Capsule (0.14ml) and 1 bottle EQUIA Coat 4ml, disposable applicators (25)
900556	10003306	GC EQUIA, Intro Pack, 50 Capsules, A3	50 Capsules EQUIA Fil (0.40g) Powder and 0.12g (0.10ml) Liquid, Mixed Volume per Capsule (0.14ml) and 1 bottle EQUIA Coat 4ml, disposable applicators (25)
900603	10003320	GC EQUIA, Intro Pack, 50 Capsules, Assorted (10 each of A2, A3, A3.5, B1, B3)	50 Capsules EQUIA Fil (0.40g) Powder and 0.12g (0.10ml) Liquid, Mixed Volume per Capsule (0.14ml) and 1 bottle EQUIA Coat 4ml, disposable applicators (25)
900559	10003307	GC EQUIA, Intro Pack, 50 Capsules, B2	50 Capsules EQUIA Fil (0.40g) Powder and 0.12g (0.10ml) Liquid, Mixed Volume per Capsule (0.14ml) and 1 bottle EQUIA Coat 4ml, disposable applicators (25)
900661	10003329	GC EQUIA, Intro Pack, 50 Capsules, SW	50 Capsules EQUIA Fil (0.40g) Powder and 0.12g (0.10ml) Liquid, Mixed Volume per Capsule (0.14ml) and 1 bottle EQUIA Coat 4ml, disposable applicators (25)
900564	10003308	GC EQUIA, Promo Pack, 100 Capsules, A2	100 Capsules EQUIA Fil (0.40g) Powder and 0.12g (0.10ml) Liquid, Mixed Volume per Capsule (0.14ml) and 1 bottle EQUIA Coat 4ml, disposable applicators (25)
900566	10003310	GC EQUIA, Promo Pack, 100 Capsules, A3	100 Capsules EQUIA Fil (0.40g) Powder and 0.12g (0.10ml) Liquid, Mixed Volume per Capsule (0.14ml) and 1 bottle EQUIA Coat 4ml, disposable applicators (25)
900565	10003309	GC EQUIA, Promo Pack, 2x50 Capsules, A2 - A3	100 Capsules EQUIA Fil (0.40g) Powder and 0.12g (0.10ml) Liquid, Mixed Volume per Capsule (0.14ml) and 1 bottle EQUIA Coat 4ml, disposable applicators (25)
900569	10003311	GC EQUIA, Promo Pack, 2x50 Capsules, B2 - A3	100 Capsules EQUIA Fil (0.40g) Powder and 0.12g (0.10ml) Liquid, Mixed Volume per Capsule (0.14ml) and 1 box EQUIA Coat 4ml, disposable applicators (25)
900662	10003330	GC EQUIA, Promo Pack, SW	100 Capsules EQUIA Fil (0.40g) Powder and 0.12g (0.10ml) Liquid, Mixed Volume per Capsule (0.14ml) and 1 bottle EQUIA Coat 4ml, disposable applicators (25)
900857	10003439	GC EQUIA, Clinic Pack, 250 Capsules, A2	250 Capsules EQUIA Fil (0.40g) Powder and 0.12g (0.10ml) Liquid, Mixed Volume per Capsule (0.14ml) and 1 bottle EQUIA Coat 6ml, Disposable applicator (25)
900858	10003440	GC EQUIA, Clinic Pack, 250 Capsules, A3	250 Capsules EQUIA Fil (0.40g) Powder and 0.12g (0.10ml) Liquid, Mixed Volume per Capsule (0.14ml) and 1 bottle EQUIA Coat 6ml, Disposable applicator (25)
900859	10003441	GC EQUIA, Clinic Pack, 250 Capsules, B2	250 Capsules EQUIA Fil (0.40g) Powder and 0.12g (0.10ml) Liquid, Mixed Volume per Capsule (0.14ml) and 1 bottle EQUIA Coat 6ml, Disposable applicator (25)





Article Code	New Article	Description	
004259	10000857	GC EQUIA Fil, Assorted Package, 50 Capsules	Box with 50 Capsules (10 pcs. each of A2, A3, A3.5, B1, B3), 0.40g Powder and 0.12g (0.10ml) Liquid, Mixed Volume per Capsule 0.14ml
004260	10000858	GC EQUIA Fil, Single Shade Pack, 50 Capsules, A1	Box with 50 Capsules, 0.40g Powder and 0.12g (0.10ml) Liquid, Mixed Volume per Capsule 0.14ml
004261	10000859	GC EQUIA Fil, Single Shade Pack, 50 Capsules, A2	Box with 50 Capsules, 0.40g Powder and 0.12g (0.10ml) Liquid, Mixed Volume per Capsule 0.14ml
004262	10000860	GC EQUIA Fil, Single Shade Pack, 50 Capsules, A3	Box with 50 Capsules, 0.40g Powder and 0.12g (0.10ml) Liquid, Mixed Volume per Capsule 0.14ml
004263	10000861	GC EQUIA Fil, Single Shade Pack, 50 Capsules, A3.5	Box with 50 Capsules, 0.40g Powder and 0.12g (0.10ml) Liquid, Mixed Volume per Capsule 0.14ml
004264	10000862	GC EQUIA Fil, Single Shade Pack, 50 Capsules, B1	Box with 50 Capsules, 0.40g Powder and 0.12g (0.10ml) Liquid, Mixed Volume per Capsule 0.14ml
004265	10000863	GC EQUIA Fil, Single Shade Pack, 50 Capsules, B2	Box with 50 Capsules, 0.40g Powder and 0.12g (0.10ml) Liquid, Mixed Volume per Capsule 0.14ml
004266	10000864	GC EQUIA Fil, Single Shade Pack, 50 Capsules, B3	Box with 50 Capsules, 0.40g Powder and 0.12g (0.10ml) Liquid, Mixed Volume per Capsule 0.14ml
004267	10000865	GC EQUIA Fil, Single Shade Pack, 50 Capsules, C4	Box with 50 Capsules, 0.40g Powder and 0.12g (0.10ml) Liquid, Mixed Volume per Capsule 0.14ml
004738	10000995	GC EQUIA Fil, Single Shade Pack, 50 Capsules, SW	Box with 50 Capsules, 0.40g Powder and 0.11g (0.09ml) Liquid, Mixed Volume per Capsule 0.14ml
004268	10000866	GC EQUIA Coat, 4ml Pack	1 Bottle EQUIA Coat 4ml & 25x disposable applicators
900584	10003315	GC EQUIA, Intro Pack, 50 Capsules, A2	50 Capsules EQUIA Fil (0.40g) Powder and 0.12g (0.10ml) Liquid, Mixed Volume per Capsule (0.14ml) and 1 bottle EQUIA Coat 4ml, disposable applicators (25)
900585	10003316	GC EQUIA, Intro Pack, 50 Capsules, A3	50 Capsules EQUIA Fil (0.40g) Powder and 0.12g (0.10ml) Liquid, Mixed Volume per Capsule (0.14ml) and 1 bottle EQUIA Coat 4ml, disposable applicators (25)
900582	10003314	GC EQUIA, Intro Pack, 50 Capsules, Assorted (10 each of A2, A3, A3.5, B1, B3)	50 Capsules EQUIA Fil (0.40g) Powder and 0.12g (0.10ml) Liquid, Mixed Volume per Capsule (0.14ml) and 1 bottle EQUIA Coat 4ml, disposable applicators (25)
900593	10003317	GC EQUIA, Promo Pack, 100 Capsules, A2	100 Capsules EQUIA Fil (0.40g) Powder and 0.12g (0.10ml) Liquid, Mixed Volume per Capsule (0.14ml) and 1 bottle EQUIA Coat 4ml, disposable applicators (25)
900595	10003319	GC EQUIA, Promo Pack, 100 Capsules, A3	100 Capsules EQUIA Fil (0.40g) Powder and 0.12g (0.10ml) Liquid, Mixed Volume per Capsule (0.14ml) and 1 bottle EQUIA Coat 4ml, disposable applicators (25)





Article Code	New Article	Description	
900594	10003318	GC EQUIA, Promo Pack, 2x50 Capsules, A2 - A3	100 Capsules EQUIA Fil (0.40g) Powder and 0.12g (0.10ml) Liquid, Mixed Volume per Capsule (0.14ml) and 1 bottle EQUIA Coat 4ml, disposable applicators (25)
900860	10003442	GC EQUIA, Clinic Pack, 250 Capsules, A2	250 Capsules EQUIA Fil (0.40g) Powder and 0.12g (0.10ml) Liquid, Mixed Volume per Capsule (0.14ml) and 1 bottle EQUIA Coat 6ml, Disposable applicator (25)
900861	10003443	GC EQUIA, Clinic Pack, 250 Capsules, A3	250 Capsules EQUIA Fil (0.40g) Powder and 0.12g (0.10ml) Liquid, Mixed Volume per Capsule (0.14ml) and 1 bottle EQUIA Coat 6ml, Disposable applicator (25)
004370	10000868	GC EQUIA Fil, Assorted Package, 50 Capsules	Box with 50 Capsules (10 pcs. each of A2, A3, A3.5, B1, B3), 0.40g Powder and 0.12g (0.10ml) Liquid, Mixed Volume per Capsule 0.14ml
004371	10000869	GC EQUIA Fil, Single Shade Pack, 50 Capsules, A1	Box with 50 Capsules, 0.40g Powder and 0.12g (0.10ml) Liquid, Mixed Volume per Capsule 0.14ml
004372	10000870	GC EQUIA Fil, Single Shade Pack, 50 Capsules, A2	Box with 50 Capsules, 0.40g Powder and 0.12g (0.10ml) Liquid, Mixed Volume per Capsule 0.14ml
004373	10000871	GC EQUIA Fil, Single Shade Pack, 50 Capsules, A3	Box with 50 Capsules, 0.40g Powder and 0.12g (0.10ml) Liquid, Mixed Volume per Capsule 0.14ml
004374	10000872	GC EQUIA Fil, Single Shade Pack, 50 Capsules, A3.5	Box with 50 Capsules, 0.40g Powder and 0.12g (0.10ml) Liquid, Mixed Volume per Capsule 0.14ml
004375	10000873	GC EQUIA Fil, Single Shade Pack, 50 Capsules, B1	Box with 50 Capsules, 0.40g Powder and 0.12g (0.10ml) Liquid, Mixed Volume per Capsule 0.14ml
004376	10000874	GC EQUIA Fil, Single Shade Pack, 50 Capsules, B2	Box with 50 Capsules, 0.40g Powder and 0.12g (0.10ml) Liquid, Mixed Volume per Capsule 0.14ml
004377	10000875	GC EQUIA Fil, Single Shade Pack, 50 Capsules, B3	Box with 50 Capsules, 0.40g Powder and 0.12g (0.10ml) Liquid, Mixed Volume per Capsule 0.14ml
004378	10000876	GC EQUIA Fil, Single Shade Pack, 50 Capsules, C4	Box with 50 Capsules, 0.40g Powder and 0.12g (0.10ml) Liquid, Mixed Volume per Capsule 0.14ml
004778	10000998	GC EQUIA Fil, Single Shade Pack, 50 Capsules, SW	Box with 50 Capsules, 0.40g Powder and 0.11g (0.09ml) Liquid, Mixed Volume per Capsule 0.14ml
004379	10000877	GC EQUIA Coat, 4ml Pack	1 Bottle EQUIA Coat 4ml & 25x disposable applicators
900737	10003381	EQUIA, Promo A3-A3 + cavity conditioner	/
900736	10003380	EQUIA, Promo A2-A3 + cavity conditioner	/
900735	10003379	EQUIA, Promo A2-A2 + cavity conditioner	/

