



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

TF 156 13 February 2019
GMDN 16704 and GMDN 45294

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

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

EQUIA Forte TM HT Fil /EQUIA Forte TM Coat

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

APPLICABLE STANDARDS

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

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,09/03/2021.....
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
901574	10004846	GC EQUIA Forte HT, Intro Pack, A2
901575	10004796	GC EQUIA Forte HT, Intro Pack, A3
901576	10004950	GC EQUIA Forte HT, Intro Pack, B2
901577	10004866	GC EQUIA Forte HT, Promo Pack, 100 Capsule, A2
901579	10004811	GC EQUIA Forte HT, Promo Pack, 100 Capsule, A3
901578	10004848	GC EQUIA Forte HT, Promo Pack, 2x50 Capsule, A2-A3
901580	10004847	GC EQUIA Forte HT, Promo Pack, 2x50 Capsule, A3-B2
901581	10004863	GC EQUIA Forte HT, Clinic Pack, 200 Capsules, A2
901582	10004892	GC EQUIA Forte HT, Clinic Pack, 200 Capsules, A3
901583	10004874	GC EQUIA Forte HT, Clinic Pack, 200 Capsules, B2
901592	10004855	GC EQUIA Forte HT, Refill Assorted Pack (10 Capsules each of A2, A3, A3.5, B1, B3)
901584	10004873	GC EQUIA Forte HT, Refill Pack, A1
901585	10004841	GC EQUIA Forte HT, Refill Pack, A2
901586	10004901	GC EQUIA Forte HT, Refill Pack, A3
901587	10004872	GC EQUIA Forte HT, Refill Pack, A3.5
901588	10004878	GC EQUIA Forte HT, Refill Pack, B1
901589	10004856	GC EQUIA Forte HT, Refill Pack, B2
901590	10004864	GC EQUIA Forte HT, Refill Pack, B3
901591	10004794	GC EQUIA Forte HT, Refill Pack, C4
901593	10004885	GC EQUIA Forte Coat, 4ml Pack
900959	10003513	GC EQUIA Forte Coat, Unit dose Pack