



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 WEP	Article Code EEP	New Article Code WEP	New Article Code EEP	Description
901574	901554	10004846	10004933	GC EQUIA Forte HT, Intro Pack, A2
901575	901555	10004796	10004808	GC EQUIA Forte HT, Intro Pack, A3
901576	901556	10004950	10004865	GC EQUIA Forte HT, Intro Pack, B2
901577	901557	10004866	10004851	GC EQUIA Forte HT, Promo Pack, 100 Capsule, A2
901579	901559	10004811	10004845	GC EQUIA Forte HT, Promo Pack, 100 Capsule, A3
901578	901558	10004848	10004882	GC EQUIA Forte HT, Promo Pack, 2x50 Capsule, A2-A3
901580	901560	10004847	10004884	GC EQUIA Forte HT, Promo Pack, 2x50 Capsule, A3-B2
901581	901561	10004863	10004903	GC EQUIA Forte HT, Clinic Pack, 200 Capsules, A2
901582	901562	10004892	10004862	GC EQUIA Forte HT, Clinic Pack, 200 Capsules, A3
901583	901563	10004874	10004890	GC EQUIA Forte HT, Clinic Pack, 200 Capsules, B2
901592	901572	10004855	10004883	GC EQUIA Forte HT, Refill Assorted Pack (10 Capsules each of A2, A3, A3.5, B1, B3)
901584	901564	10004873	10004781	GC EQUIA Forte HT, Refill Pack, A1
901585	901565	10004841	10004859	GC EQUIA Forte HT, Refill Pack, A2
901586	901566	10004901	10004861	GC EQUIA Forte HT, Refill Pack, A3
901587	901567	10004872	10004959	GC EQUIA Forte HT, Refill Pack, A3.5





901588	901568	10004878	10004880	GC EQUIA Forte HT, Refill Pack, B1
901589	901569	10004856	10004923	GC EQUIA Forte HT, Refill Pack, B2
901590	901570	10004864	10004843	GC EQUIA Forte HT, Refill Pack, B3
901591	901571	10004794	10004803	GC EQUIA Forte HT, Refill Pack, C4
901593	901573	10004885	10004849	GC EQUIA Forte Coat, 4ml Pack
900959	900960	10003513	10003514	GC EQUIA Forte Coat, Unit dose Pack