EC DECLARATION OF CONFORMITY
According to Annex V and 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 ™ HT Fil /EQUIA Forte ™ Coat

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

APPLICABLE STANDARDS

EQUIA Forte ™ HT Fil (GMDN code:16704)

- 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

EQUIA Forte ™ Coat (GMDN code: 45294)

- Company specification: AB-15-Q-301-638
- 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.

EQUIA Forte ™ HT Fil /EQUIA Forte ™ Coat is Class IIa according to rule 5 of annex IX of the Council Directive.

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

Leuven, 14 February 2019 .....

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

LIST OF PRODUCTS

	Article code	Description
1	901554	GC EQUIA Forte HT, Intro Pack, A2 EEP
2	901555	GC EQUIA Forte HT, Intro Pack, A3 EEP
3	901556	GC EQUIA Forte HT, Intro Pack, B2 EEP
4	901557	GC EQUIA Forte HT, Promo Pack, A2 EEP
5	901558	GC EQUIA Forte HT, Promo Pack, A2-A3 EEP
6	901559	GC EQUIA Forte HT, Promo Pack, A3 EEP
7	901560	GC EQUIA Forte HT, Promo Pack, A3-B2 EEP
8	901561	GC EQUIA Forte HT, Clinic Pack, A2 EEP
9	901562	GC EQUIA Forte HT, Clinic Pack, A3 EEP
10	901563	GC EQUIA Forte HT, Clinic Pack, B2 EEP
11	901564	GC EQUIA Forte HT, Refill Pack, A1 EEP
12	901565	GC EQUIA Forte HT, Refill Pack, A2 EEP
13	901566	GC EQUIA Forte HT, Refill Pack, A3 EEP
14	901567	GC EQUIA Forte HT, Refill Pack, A3.5 EEP
15	901568	GC EQUIA Forte HT, Refill Pack, B1 EEP
16	901569	GC EQUIA Forte HT, Refill Pack, B2 EEP
17	901570	GC EQUIA Forte HT, Refill Pack, B3 EEP
18	901571	GC EQUIA Forte HT, Refill Pack, C4 EEP
19	901572	GC EQUIA Forte HT, Assorted Pack EEP
20	901573	GC EQUIA Forte Coat FlipCap 4ml Pack EEP
21	901574	GC EQUIA Forte HT, Intro Pack, A2 WEP
22	901575	GC EQUIA Forte HT, Intro Pack, A3 WEP
23	901576	GC EQUIA Forte HT, Intro Pack, B2 WEP
24	901577	GC EQUIA Forte HT, Promo Pack, A2 WEP
25	901578	GC EQUIA Forte HT, Promo Pack, A2-A3 WEP
26	901579	GC EQUIA Forte HT, Promo Pack, A3 WEP
27	901580	GC EQUIA Forte HT, Promo Pack, A3-B2 WEP
28	901581	GC EQUIA Forte HT, Clinic Pack, A2 WEP
29	901582	GC EQUIA Forte HT, Clinic Pack, A3 WEP
30	901583	GC EQUIA Forte HT, Clinic Pack, B2 WEP
31	901584	GC EQUIA Forte HT, Refill Pack, A1 WEP
32	901585	GC EQUIA Forte HT, Refill Pack, A2 WEP
33	901586	GC EQUIA Forte HT, Refill Pack, A3 WEP
34	901587	GC EQUIA Forte HT, Refill Pack, A3.5 WEP
35	901588	GC EQUIA Forte HT, Refill Pack, B1 WEP
36	901589	GC EQUIA Forte HT, Refill Pack, B2 WEP
37	901590	GC EQUIA Forte HT, Refill Pack, B3 WEP

38	901591	GC EQUIA Forte HT, Refill Pack, C4 WEP
39	901592	GC EQUIA Forte HT, Assorted Pack WEP
40	901593	GC EQUIA Forte Coat FlipCap 4ml Pack WEP
41	890464	GC EQUIA Forte Ht, Sample Pack, A2 WEP
42	890465	GC EQUIA Forte Ht, Sample Pack, A2 EEP
43	890466	GC EQUIA Forte Ht, Sample Pack, A3 WEP
44	890467	GC EQUIA Forte Ht, Sample Pack,A3 EEP
45	890468	GC EQUIA Forte Ht, Sample Pack,B2 WEP
46	890469	GC EQUIA Forte Ht, Sample Pack,B2EEP