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

TF76 4 Oct 2010
GMDN 38764

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

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

G-aenial Universal Flo

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

ISO 4049: 2000 Dentistry – Polymer-based filling, restorative and luting materials

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.

G-aenial Universal Flo is Class IIa according to rule 5 of annex IX of the Council Directive.

Notified Body: British Standards Institution (n°0086).

Leuven, ...25/04/2016.....
Date

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

LIST OF PRODUCTS

Article code	Description
004202	G-aenial Universal Flo,A1,1 syringe
004203	G-aenial Universal Flo,A2,1 syringe
004204	G-aenial Universal Flo,A3,1 syringe
004205	G-aenial Universal Flo,A3,5 1 syringe
004206	G-aenial Universal Flo,A4 ,1 syringe
004207	G-aenial Universal Flo,B1,1 syringe
004208	G-aenial Universal Flo,B2 ,1 syringe
004209	G-aenial Universal Flo,B3 ,1 syringe
004210	G-aenial Universal Flo,C3 ,1 syringe
004211	G-aenial Universal Flo,AO2,1 syringe
004212	G-aenial Universal Flo,AO3 ,1 syringe
004213	G-aenial Universal Flo,BW ,1 syringe
004214	G-aenial Universal Flo,CV,1 syringe
004215	G-aenial Universal Flo,JE ,1 syringe
004216	G-aenial Universal Flo,AE ,1 syringe
004619	G-aenial Universal Flo,A1,1 syringe,EEP
004620	G-aenial Universal Flo,A2,1 syringe,EEP
004621	G-aenial Universal Flo,A3,1 syringe,EEP
004622	G-aenial Univ.Flo,A3.5,1 syringe,EEP
004623	G-aenial Universal Flo,A4,1 syringe,EEP
004624	G-aenial Universal Flo,B1,1 syringe,EEP
004625	G-aenial Universal Flo,B2,1 syringe,EEP
004626	G-aenial Universal Flo,B3,1 syringe,EEP
004627	G-aenial Universal Flo,C3,1 syringe,EEP
004628	G-aenial Univ.Flo,AO2,1 syringe,EEP
004629	G-aenial Univ.Flo,AO3,1 syringe,EEP
004630	G-aenial Universal Flo,BW,1 syringe,EEP
004631	G-aenial Universal Flo,CV,1 syringe,EEP
004632	G-aenial Universal Flo,JE ,1 syringe,EEP
004633	G-aenial Universal Flo,AE ,1 syringe,EEP
004774	G-aenial Univ Flo A2 Sample 1 GR
004775	G-aenial Univ Flo A3 Sample 1 GR
900695	G-aenial Univ Flo A2 + Bond promo pack
900696	G-aenial Univ Flo A3 + Bond promo pack