



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

TF76 4 Oct 2010

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: 2019 Dentistry – Polymer-based Restorative Materials

**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.

G-aenial Universal Flo is Class IIa according to rule 8 of annex IX of the Council Directive.

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

Leuven,27/01/2022.....
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
004202	10000838	G-ænia Universal Flo, Syringe 2ml (3.4g), A1 + 20x Dispensing Tip III Plastic, 1x light protective cover
004203	10000839	G-ænia Universal Flo, Syringe 2ml (3.4g), A2 + 20x Dispensing Tip III Plastic, 1x light protective cover
004204	10000840	G-ænia Universal Flo, Syringe 2ml (3.4g), A3 + 20x Dispensing Tip III Plastic, 1x light protective cover
004205	10000841	G-ænia Universal Flo, Syringe 2ml (3.4g), A3.5 + 20x Dispensing Tip III Plastic, 1x light protective cover
004206	10000842	G-ænia Universal Flo, Syringe 2ml (3.4g), A4 + 20x Dispensing Tip III Plastic, 1x light protective cover
004207	10000843	G-ænia Universal Flo, Syringe 2ml (3.4g), B1 + 20x Dispensing Tip III Plastic, 1x light protective cover
004208	10000844	G-ænia Universal Flo, Syringe 2ml (3.4g), B2 + 20x Dispensing Tip III Plastic, 1x light protective cover
004209	10000845	G-ænia Universal Flo, Syringe 2ml (3.4g), B3 + 20x Dispensing Tip III Plastic, 1x light protective cover
004210	10000846	G-ænia Universal Flo, Syringe 2ml (3.4g), C3 + 20x Dispensing Tip III Plastic, 1x light protective cover
004211	10000847	G-ænia Universal Flo, Syringe 2ml (3.4g), AO2 + 20x Dispensing Tip III Plastic, 1x light protective cover
004212	10000848	G-ænia Universal Flo, Syringe 2ml (3.4g), AO3 + 20x Dispensing Tip III Plastic, 1x light protective cover
004213	10000849	G-ænia Universal Flo, Syringe 2ml (3.4g), BW + 20x Dispensing Tip III Plastic, 1x light protective cover
004214	10000850	G-ænia Universal Flo, Syringe 2ml (3.4g), CV + 20x Dispensing Tip III Plastic, 1x light protective cover
004215	10000851	G-ænia Universal Flo, Syringe 2ml (3.4g), JE + 20x Dispensing Tip III Plastic, 1x light protective cover
004216	10000852	G-ænia Universal Flo, Syringe 2ml (3.4g), AE





		+ 20x Dispensing Tip III Plastic, 1x light protective cover
004619	10000915	G-æniel Universal Flo, Syringe 2ml (3.4g), A1 + 20x Dispensing Tip III Plastic, 1x light protective cover
004620	10000916	G-æniel Universal Flo, Syringe 2ml (3.4g), A2 + 20x Dispensing Tip III Plastic, 1x light protective cover
004621	10000917	G-æniel Universal Flo, Syringe 2ml (3.4g), A3 + 20x Dispensing Tip III Plastic, 1x light protective cover
004622	10000918	G-æniel Universal Flo, Syringe 2ml (3.4g), A3.5 + 20x Dispensing Tip III Plastic, 1x light protective cover
004623	10000919	G-æniel Universal Flo, Syringe 2ml (3.4g), A4 + 20x Dispensing Tip III Plastic, 1x light protective cover
004624	10000920	G-æniel Universal Flo, Syringe 2ml (3.4g), B1 + 20x Dispensing Tip III Plastic, 1x light protective cover
004625	10000921	G-æniel Universal Flo, Syringe 2ml (3.4g), B2 + 20x Dispensing Tip III Plastic, 1x light protective cover
004626	10000922	G-æniel Universal Flo, Syringe 2ml (3.4g), B3 + 20x Dispensing Tip III Plastic, 1x light protective cover
004627	10000923	G-æniel Universal Flo, Syringe 2ml (3.4g), C3 + 20x Dispensing Tip III Plastic, 1x light protective cover
004628	10000924	G-æniel Universal Flo, Syringe 2ml (3.4g), AO2 + 20x Dispensing Tip III Plastic, 1x light protective cover
004629	10000925	G-æniel Universal Flo, Syringe 2ml (3.4g), AO3 + 20x Dispensing Tip III Plastic, 1x light protective cover
004630	10000926	G-æniel Universal Flo, Syringe 2ml (3.4g), BW + 20x Dispensing Tip III Plastic, 1x light protective cover
004631	10000927	G-æniel Universal Flo, Syringe 2ml (3.4g), CV + 20x Dispensing Tip III Plastic, 1x light protective cover
004632	10000928	G-æniel Universal Flo, Syringe 2ml (3.4g), JE + 20x Dispensing Tip III Plastic, 1x light protective cover
004633	10000929	G-æniel Universal Flo, Syringe 2ml (3.4g), AE + 20x Dispensing Tip III Plastic, 1x light protective cover
004774	10000996	G-aenial Univ Flo A2 Sample 1 GR
004775	10000997	G-aenial Univ Flo A3 Sample 1 GR





900695	10003352	G-aenial Univ Flo A2 + Bond promo pack
900696	10003353	G-aenial Univ Flo A3 + Bond promo pack
901422	10003659	G-ænia Universal Flo A2 + G-Premio BOND Promo Pack
901423	10003660	G-ænia Universal Flo A3 + G-Premio BOND Promo Pack
011939*	10006095	G-aenial Universal Flo, AO1 AU

(*) article available only for Oceania