



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

TF147

09 March 2018

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 Injectable

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

EN ISO 13485:2016

**Medical devices -- Quality management systems -
Requirements for regulatory purposes**

ISO 4049:2019

Dentistry – Polymer-based restorative 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.

This product 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.....

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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
901471	10003703	G-ænia Universal Injectable, Syringe 1ml (1.7g), XBW
901472	10003704	G-ænia Universal Injectable, Syringe 1ml (1.7g), BW
901473	10003705	G-ænia Universal Injectable, Syringe 1ml (1.7g), A1
901474	10003706	G-ænia Universal Injectable, Syringe 1ml (1.7g), A2
901475	10003707	G-ænia Universal Injectable, Syringe 1ml (1.7g), A3
901476	10003708	G-ænia Universal Injectable, Syringe 1ml (1.7g), A3.5
901477	10003709	G-ænia Universal Injectable, Syringe 1ml (1.7g), A4
901478	10003710	G-ænia Universal Injectable, Syringe 1ml (1.7g), B1
901479	10003711	G-ænia Universal Injectable, Syringe 1ml (1.7g), B2
901480	10003712	G-ænia Universal Injectable, Syringe 1ml (1.7g), CV
901481	10003713	G-ænia Universal Injectable, Syringe 1ml (1.7g), CVD
901482	10003714	G-ænia Universal Injectable, Syringe 1ml (1.7g), AO1
901483	10003715	G-ænia Universal Injectable, Syringe 1ml (1.7g), AO2
901484	10003716	G-ænia Universal Injectable, Syringe 1ml (1.7g), AO3
901485	10003717	G-ænia Universal Injectable, Syringe 1ml (1.7g), JE
901486	10003718	G-ænia Universal Injectable, Syringe 1ml (1.7g), AE
901487	10003719	G-ænia Universal Injectable, Syringe 1ml (1.7g), XBW
901488	10003720	G-ænia Universal Injectable, Syringe 1ml (1.7g), BW
901489	10003721	G-ænia Universal Injectable, Syringe 1ml (1.7g), A1
901490	10003722	G-ænia Universal Injectable, Syringe 1ml (1.7g), A2
901491	10003723	G-ænia Universal Injectable, Syringe 1ml (1.7g), A3
901492	10003724	G-ænia Universal Injectable, Syringe 1ml (1.7g), A3.5
901493	10003725	G-ænia Universal Injectable, Syringe 1ml (1.7g), A4



901494	10003726	G-ænia Universal Injectable, Syringe 1ml (1.7g), B1
901495	10003727	G-ænia Universal Injectable, Syringe 1ml (1.7g), B2
901496	10003728	G-ænia Universal Injectable, Syringe 1ml (1.7g), CV
901497	10003729	C G-ænia Universal Injectable, Syringe 1ml (1.7g), CVD
901498	10003730	G-ænia Universal Injectable, Syringe 1ml (1.7g), AO1
901499	10003731	G-ænia Universal Injectable, Syringe 1ml (1.7g), AO2
901500	10003732	G-ænia Universal Injectable, Syringe 1ml (1.7g), AO3
901501	10003733	G-ænia Universal Injectable, Syringe 1ml (1.7g), JE
901502	10003734	G-ænia Universal Injectable, Syringe 1ml (1.7g), AE
013047	10006896	G-ænia Universal Injectable, Unitip 15x0.16mL (0.27g), A1
013048	10006897	G-ænia Universal Injectable, Unitip 15x0.16mL (0.27g), A2
013049	10006898	G-ænia Universal Injectable, Unitip 15x0.16mL (0.27g), A3
013050	10006899	G-ænia Universal Injectable, Unitip 15x0.16mL (0.27g), A3.5
013051	10006900	G-ænia Universal Injectable, Unitip 15x0.16mL (0.27g), A4
013052	10006901	G-ænia Universal Injectable, Unitip 15x0.16mL (0.27g), B1
013053	10006902	G-ænia Universal Injectable, Unitip 15x0.16mL (0.27g), B2
013054	10006903	G-ænia Universal Injectable, Unitip 15x0.16mL (0.27g), CV
013055	10006904	G-ænia Universal Injectable, Unitip 15x0.16mL (0.27g), CVD
013056	10006905	G-ænia Universal Injectable, Unitip 15x0.16mL (0.27g), AO1
013057	10006906	G-ænia Universal Injectable, Unitip 15x0.16mL (0.27g), AO2
013058	10006907	G-ænia Universal Injectable, Unitip 15x0.16mL (0.27g), AO3
013059	10006908	G-ænia Universal Injectable, Unitip 15x0.16mL (0.27g), JE
013060	10006909	G-ænia Universal Injectable, Unitip 15x0.16mL (0.27g), AE
013061	10006910	G-ænia Universal Injectable, Unitip 15x0.16mL (0.27g), XBW
013062	10006911	G-ænia Universal Injectable, Unitip 15x0.16mL (0.27g), BW



901509	10003741	G-ænial Universal Injectable (3x)+ G-Premio Bond Kit Promo
/	10006971	G-ænial Universal Injectable SAMPLE (unitips)
901616	10004850	G-ænial Universal Injectable A2 PROMO PACK (2XA2)
901617	10004858	G-ænial Universal Injectable A3 PROMO PACK (2XA3)