



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

TF 74 22 March 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

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.

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	New Article code	Description
003908	10000772	G-ænial, Quick Start Kit Unitip Including 1 Shade Guide and 35 Unitips: 5x A1, A2, A3, B2, JE, AE, IE of 0.16ml (0.28g) each
003909	10000773	G-ænial, Quick Start Kit Syringe Including 1 Shade Guide and 7 Syringes: 1x A1, A2, A3, B2, JE, AE, IE of 2.7ml (4.7g) each
003911	10000775	G-ænial Anterior, Unitip 20x0.16ml (0.28g), A1
003912	10000776	G-ænial Anterior, Unitip 20x0.16ml (0.28g), A2
003913	10000777	G-ænial Anterior, Unitip 20x0.16ml (0.28g), A3
003914	10000778	G-ænial Anterior, Unitip 20x0.16ml (0.28g), A3.5
003915	10000779	G-ænial Anterior, Unitip 20x0.16ml (0.28g), AO3
003916	10000780	G-ænial Anterior, Unitip 20x0.16ml (0.28g), CV
003917	10000781	G-ænial Anterior, Unitip 20x0.16ml (0.28g), AE
003918	10000782	G-ænial Anterior, Unitip 20x0.16ml (0.28g), IE
003919	10000783	G-ænial Anterior, Unitip 10x0.16ml (0.28g), BW
003920	10000784	G-ænial Anterior, Unitip 10x0.16ml (0.28g), A4
003921	10000785	G-ænial Anterior, Unitip 10x0.16ml (0.28g), B2
003922	10000786	G-ænial Anterior, Unitip 10x0.16ml (0.28g), B3
003923	10000787	G-ænial Anterior, Unitip 10x0.16ml (0.28g), C3
003924	10000788	G-ænial Anterior, Unitip 10x0.16ml (0.28g), CVD
003925	10000789	G-ænial Anterior, Unitip 10x0.16ml (0.28g), AO2
003926	10000790	G-ænial Anterior, Unitip 10x0.16ml (0.28g), AO4
003927	10000791	G-ænial Anterior, Unitip 10x0.16ml (0.28g), JE
003928	10000792	G-ænial Anterior, Unitip 10x0.16ml (0.28g), TE
003929	10000793	G-ænial Anterior, Unitip 10x0.16ml (0.28g), SE
003930	10000794	G-ænial Anterior, Unitip 10x0.16ml (0.28g), CVE
003931	10000795	G-ænial Anterior, Unitip 10x0.16ml (0.28g), XBW
003932	10000796	G-ænial Anterior, Unitip 10x0.16ml (0.28g), B1
003933	10000797	G-ænial Posterior, Unitip 20x0.16ml (0.33g), P-A1
003934	10000798	G-ænial Posterior, Unitip 20x0.16ml (0.33g), P-A2
003935	10000799	G-ænial Posterior, Unitip 20x0.16ml (0.33g), P-A3
003936	10000800	G-ænial Posterior, Unitip 20x0.16ml (0.33g), P-A3.5
003937	10000801	G-ænial Posterior, Unitip 20x0.16ml (0.33g), P-JE
003938	10000802	G-ænial Posterior, Unitip 20x0.16ml (0.33g), P-IE
003939	10000803	G-ænial Anterior, Syringe 2.7ml (4.7g), BW
003940	10000804	G-ænial Anterior, Syringe 2.7ml (4.7g), A1
003941	10000805	G-ænial Anterior, Syringe 2.7ml (4.7g), A2
003942	10000806	G-ænial Anterior, Syringe 2.7ml (4.7g), A3
003943	10000807	G-ænial Anterior, Syringe 2.7ml (4.7g), A3.5
003944	10000808	G-ænial Anterior, Syringe 2.7ml (4.7g), A4
003945	10000809	G-ænial Anterior, Syringe 2.7ml (4.7g), B2
003946	10000810	G-ænial Anterior, Syringe 2.7ml (4.7g), B3



003947	1000811	G-ænia Anterior, Syringe 2.7ml (4.7g), C3
003948	1000812	G-ænia Anterior, Syringe 2.7ml (4.7g), CV
003949	1000813	G-ænia Anterior, Syringe 2.7ml (4.7g), CVD
003950	1000814	G-ænia Anterior, Syringe 2.7ml (4.7g), AO2
003951	1000815	G-ænia Anterior, Syringe 2.7ml (4.7g), AO3
003952	1000816	G-ænia Anterior, Syringe 2.7ml (4.7g), AO4
003953	1000817	G-ænia Anterior, Syringe 2.7ml (4.7g), JE
003954	1000818	G-ænia Anterior, Syringe 2.7ml (4.7g), AE
003955	1000819	G-ænia Anterior, Syringe 2.7ml (4.0g), TE
003956	1000820	G-ænia Anterior, Syringe 2.7ml (4.7g), IE
003957	1000821	G-ænia Anterior, Syringe 2.7ml (4.7g), SE
003958	1000822	G-ænia Anterior, Syringe 2.7ml (4.7g), CVE
003959	1000823	G-ænia Anterior, Syringe 2.7ml (4.7g), XBW
003960	1000824	G-ænia Anterior, Syringe 2.7ml (4.7g), B1
003961	1000825	G-ænia Posterior, Syringe 2.7ml (5.5g), P-A1
003962	1000826	G-ænia Posterior, Syringe 2.7ml (5.5g), P-A2
003963	1000827	G-ænia Posterior, Syringe 2.7ml (5.5g), P-A3
003964	1000828	G-ænia Posterior, Syringe 2.7ml (5.5g), P-A3.5
003965	1000829	G-ænia Posterior, Syringe 2.7ml (5.5g), P-JE
003966	1000830	G-ænia Posterior, Syringe 2.7ml (5.5g), P-IE
004649	1000936	G-ænia Anterior, Unitip 20x0.16ml (0.28g), A1
004650	1000937	G-ænia Anterior, Unitip 20x0.16ml (0.28g), A2
004651	1000938	G-ænia Anterior, Unitip 20x0.16ml (0.28g), A3
004652	1000939	G-ænia Anterior, Unitip 20x0.16ml (0.28g), A3.5
004653	1000940	G-ænia Anterior, Unitip 20x0.16ml (0.28g), AO3
004654	1000941	G-ænia Anterior, Unitip 20x0.16ml (0.28g), CV
004655	1000942	G-ænia Anterior, Unitip 20x0.16ml (0.28g), AE
004656	1000943	G-ænia Anterior, Unitip 20x0.16ml (0.28g), IE
004657	1000944	G-ænia Anterior, Unitip 10x0.16ml (0.28g), BW
004658	1000945	G-ænia Anterior, Unitip 10x0.16ml (0.28g), A4
004659	1000946	G-ænia Anterior, Unitip 10x0.16ml (0.28g), B2
004660	1000947	G-ænia Anterior, Unitip 10x0.16ml (0.28g), B3
004661	1000948	G-ænia Anterior, Unitip 10x0.16ml (0.28g), C3
004662	1000949	G-ænia Anterior, Unitip 10x0.16ml (0.28g), CVD
004663	1000950	G-ænia Anterior, Unitip 10x0.16ml (0.28g), AO2
004664	1000951	G-ænia Anterior, Unitip 10x0.16ml (0.28g), AO4
004665	1000952	G-ænia Anterior, Unitip 10x0.16ml (0.28g), JE
004666	1000953	G-ænia Anterior, Unitip 10x0.16ml (0.28g), TE
004667	1000954	G-ænia Anterior, Unitip 10x0.16ml (0.28g), SE
004668	1000955	G-ænia Anterior, Unitip 10x0.16ml (0.28g), CVE
004669	1000956	G-ænia Anterior, Unitip 10x0.16ml (0.28g), XBW
004670	1000957	G-ænia Anterior, Unitip 10x0.16ml (0.28g), B1
004671	1000958	G-ænia Posterior, Unitip 20x0.16ml (0.33g), P-A1
004672	1000959	G-ænia Posterior, Unitip 20x0.16ml (0.33g), P-A2
004673	1000960	G-ænia Posterior, Unitip 20x0.16ml (0.33g), P-A3
004674	1000961	G-ænia Posterior, Unitip 20x0.16ml (0.33g), P-A3.5
004675	1000962	G-ænia Posterior, Unitip 20x0.16ml (0.33g), P-JE
004676	1000963	G-ænia Posterior, Unitip 20x0.16ml (0.33g), P-IE
004677	1000964	G-ænia Anterior, Syringe 2.7ml (4.7g), BW



004678	10000965	G-ænia Anterior, Syringe 2.7ml (4.7g), A1
004679	10000966	G-ænia Anterior, Syringe 2.7ml (4.7g), A2
004680	10000967	G-ænia Anterior, Syringe 2.7ml (4.7g), A3
004681	10000968	G-ænia Anterior, Syringe 2.7ml (4.7g), A3.5
004682	10000969	G-ænia Anterior, Syringe 2.7ml (4.7g), A4
004683	10000970	G-ænia Anterior, Syringe 2.7ml (4.7g), B2
004684	10000971	G-ænia Anterior, Syringe 2.7ml (4.7g), B3
004685	10000972	G-ænia Anterior, Syringe 2.7ml (4.7g), C3
004686	10000973	G-ænia Anterior, Syringe 2.7ml (4.7g), CV
004687	10000974	G-ænia Anterior, Syringe 2.7ml (4.7g), CVD
004688	10000975	G-ænia Anterior, Syringe 2.7ml (4.7g), AO2
004689	10000976	G-ænia Anterior, Syringe 2.7ml (4.7g), AO3
004690	10000977	G-ænia Anterior, Syringe 2.7ml (4.7g), AO4
004691	10000978	G-ænia Anterior, Syringe 2.7ml (4.7g), JE
004692	10000979	G-ænia Anterior, Syringe 2.7ml (4.7g), AE
004693	10000980	G-ænia Anterior, Syringe 2.7ml (4.0g), TE
004694	10000981	G-ænia Anterior, Syringe 2.7ml (4.7g), IE
004695	10000982	G-ænia Anterior, Syringe 2.7ml (4.7g), SE
004696	10000983	G-ænia Anterior, Syringe 2.7ml (4.7g), CVE
004697	10000984	G-ænia Anterior, Syringe 2.7ml (4.7g), XBW
004698	10000985	G-ænia Anterior, Syringe 2.7ml (4.7g), B1
004699	10000986	G-ænia Posterior, Syringe 2.7ml (5.5g), P-A1
004700	10000987	G-ænia Posterior, Syringe 2.7ml (5.5g), P-A2
004701	10000988	G-ænia Posterior, Syringe 2.7ml (5.5g), P-A3
004702	10000989	G-ænia Posterior, Syringe 2.7ml (5.5g), P-A3.5
004703	10000990	G-ænia Posterior, Syringe 2.7ml (5.5g), P-JE
004704	10000991	G-ænia Posterior, Syringe 2.7ml (5.5g), P-IE
900537	10003303	G-ænia Unitip IE-A02-A2-AE sample kit
900607	10003322	G-ænia Unitip A2-A3-PA3 sample kit
901418	10003655	G-ænia Syringe + G-Premio BOND Promo Pack
901419	10003656	G-ænia Unitip + G-Premio BOND Promo Pack
901611	10004947	G-ænia Anterior A2-A3 Syringe Promo Pack.
901612	10004951	G-ænia Posterior PA2-PA3 Syringe Promo Pack
901613	10004870	G-ænia Anterior A2-A3 Unitip Promo Pack
901614	10004875	G-ænia Posterior PA2-PA3 Unitip Promo Pack