



EU-KONFORMITÄTSERKLÄRUNG
EU DECLARATION OF CONFORMITY
DÉCLARATION UE DE CONFORMITÉ
DICHIARAZIONE DI CONFORMITA' UE
ES ATBILSTĪBAS DEKLARĀCIJA
DECLARAÇÃO DE CONFORMIDADE UE
IZJAVA EU O SKLADNOSTI
AB UYGUNLUK BEYANIEC DECLARATION OF CONFORMITY

Gemäß Anhang XI - Teil A der Verordnung (EU) 2017/745
According to Annex XI – Part A of Regulation (EU) 2017/745
Conformément à l'Annexe XI – Partie A du Règlement (UE) 2017/745
Secondo l'Allegato XI-Parte A del Regolamento (UE) 2017/45
Saskaņā ar regulas (EU) 2017/745 A daļas pielikumu XI
De acordo com os Anexo XI - Parte A do Regulamento (UE) 2017/745
V skladu s Prilogo XI – del A Uredbe (EU) 2017/745
(AB) 2017/745 sayılı Tüzüğün Ek XI - Bölüm A'sına göre

GC EUROPE N.V.

Interleuvenlaan 33
3001 Leuven
Belgium

SRN: BE-MF-000001608

-Wir versichern und erklären in alleiniger Verantwortung, dass das Produkt:
-We ensure and declare under our sole responsibility that the product:
-Nous assurons et déclarons sous notre seule responsabilité que le produit:
-Si attesta e dichiara sotto la responsabilità esclusiva che il prodotto:
-Mēs apliecinām un deklarējam, uzņemoties pilnu atbildību, ka produkts:
-Garantimos e declaramos sob a nossa exclusiva responsabilidade que o produto:
-S polno odgovornostjo zagotavljamo in izjavljamo, da izdelek:
-Tamamen kendi sorumluluğumuz altında ürünün aşağıdaki özelliklere sahip olduğunu garanti ve beyan ederiz:

Produktname Product Name Nom du produit Nome del prodotto Produkta nosaukums Nome do produto Ime izdelka	G-aenial
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Ürün Adı	
Verwendungszweck Intended Purpose Usage prévu Uso inteso Izmantošanas mērķis Finalidade prevista Predvideni Namen Hedeflenen Amaç	Light-cured radiopaque composite restorative
Klassifizierung gemäß Anhang VIII der Verordnung (EU) 2017/745 Classification according to Annex VIII of the Regulation (EU) 2017/745 Classification selon l'Annexe VIII du Règlement (UE) 2017/745 Classificazione secondo l'Allegato VIII del Regolamento 2017/745 Klasifikācija saskaņā ar regulas (EU) 2017/745 pielikumu VIII Classificação de acordo com o Anexo VIII do Regulamento (UE) 2017/745 Razred tveganja v skladu s Prilogo VIII k Uredbi (EU) 2017/745 (AB) 2017/745 sayılı Tüzüğün Ek VIII'ine göre sınıflandırma	Klasse; Class; Classe; Classe; Klase; Classe; Razred tveganja; Sınıf IIa Regel; Rule; Règle; Regola; Likums; Regra; Pravilo; Kural 8, 19
Artikelliste Article List Liste des articles Lista degli Articoli Artikulu saraksts Lista de Artigos Seznam kod izdelkov Makale Listesi	Gemäß Anhang According to the Attachment Conformément à la pièce jointe Secondo l'Allegato Saskaņā ar pielikumu De acordo com o Anexo V skladu s Prilogo Ek'e göre
Basis-UDI-DI Basic UDI-DI IUD-ID de base UDI-DI base UDI-DI bāze	++J022MD0032JX





UDI-DI básico Osnovni UDI-DI Temel UDI-DI	
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-auf das sich diese Erklärung bezieht, mit den folgenden Normen oder anderen normativen Dokumenten übereinstimmt:

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

-auquel se rapporte cette déclaration est conforme aux normes ou autres documents normatifs suivants :

-al quale questa dichiarazione si riferisce, è in conformità ai seguenti standards o altri documenti normativi:

-attiecībā uz to, uz kuru dotā deklarācija attiecas, ir atbilstoša sekojošiem standartiem vai citiem normatīviem dokumentiem:

-a que se refere a presente declaração está em conformidade com as seguintes normas ou outros documentos normativos:

-na katere se nanaša ta izjava, je v skladu z naslednjimi standardi ali drugimi normativnimi dokumenti:

-Bu beyanin ilgili olduğu aşağıdaki standartlara veya diğer normatif belgelere uygundur:

EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes

ISO 4049:2019 Dentistry – Polymer based restorative materials

-und die zutreffenden geltenden Bestimmungen der Verordnung (EU) 2017/745 über Medizinprodukte erfüllt und in Übereinstimmung mit der technischen Dokumentation hergestellt wurde

-and meets the provisions of Regulation (EU) 2017/745 concerning Medical Devices which apply to it, and is manufactured in accordance with the technical documentation

-et répond aux dispositions du Règlement (UE) 2017/745 concernant les Dispositifs Médicaux qui lui sont applicables, et est fabriqué conformément à la documentation technique

-e soddisfa i requisiti del Regolamento (UE) 2017/745 relativo ai Dispositivi Medici che si applica ad esso, ed è fabbricato in conformità alla documentazione tecnica

-atbilst regulas (EU) 2017/745 prasībām attiecībā uz medicīnas ierīcēm un ir izgatavots saskaņā ar tehnisko dokumentāciju

-e cumpre as disposições do Regulamento (UE) 2017/745 relativo aos Dispositivos Médicos que lhe são aplicáveis, e é fabricado em conformidade com a Documentação Técnica

-in izpolnjuje določbe Uredbe (EU) 2017/745 o medicinskih pripomočkih, ki se zanj uporabljajo, ter je proizveden v skladu s tehnično dokumentacijo

-ve Tıbbi Cihazlara ilişkin (AB) 2017/745 sayılı Tüzüğün kendisi için geçerli olan hükümlerini karşılar ve teknik belgelere uygun olarak üretilmiştir





Benannte Stelle; Notified Body; Organisme notifié; Ente Notificato; Atbildīgā iestāde; Organismo Notificado; Priglašeni Organ; Onaylanmış Kuruluş

British Standards Institution, Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands (n° 2797);

Zertifikat; Certificate; Certificat; Certificato; Sertifikāts; Certificado; Certifikat; Sertifika

MDR 778483

Leuven, ...12 February 2026.....

Datum; Date; Date; Data; Datums; Data; Datum; Tarihler

.....
Mario Minale

Head of Regulatory Affairs

Im Namen von GC Europe N.V.; On behalf of GC EUROPE N.V.; Au nom de GC EUROPE N.V.; Per conto della GC Europe N.V.; GC EUROPE N.V. vārdā; Pela GC EUROPE N.V.; V imenu GC EUROPE N.V.; GC EUROPE N.V. adına



Produktverzeichnis; List of Products; Liste des produits; Lista dei Prodotti; Produktu saraksts; Lista de Produtos; Seznam Izdelkov; Ürün Listesi

Basis-UDI-DI Basic UDI-DI IUD-ID de base UDI-DI base UDI-DI bāze UDI-DI básico Osnovni UDI-DI Temel UDI-DI	Artikel- Code Article Code Code article Codice Articolo Artikuls Código do artigo Koda Izdelka Madde Kodu	Neuer Artikel-Code New Article code code Nouveau code article Nuovo Codice articolo Jaunais artikuls Novo código do artigo Nova Koda Izdelka Yeni Makale kodu	Beschreibung Description Description Descrizione Apraksts Descrição Opis Açıklama
++J022MD0032JX	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
++J022MD0032JX	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
++J022MD0032JX	003911	10000775	G-ænial Anterior, Unitip 20x0.16ml (0.28g), A1
++J022MD0032JX	003912	10000776	G-ænial Anterior, Unitip 20x0.16ml (0.28g), A2
++J022MD0032JX	003913	10000777	G-ænial Anterior, Unitip 20x0.16ml (0.28g), A3
++J022MD0032JX	003914	10000778	G-ænial Anterior, Unitip 20x0.16ml (0.28g), A3.5
++J022MD0032JX	003915	10000779	G-ænial Anterior, Unitip 20x0.16ml (0.28g), AO3
++J022MD0032JX	003916	10000780	G-ænial Anterior, Unitip 20x0.16ml (0.28g), CV
++J022MD0032JX	003917	10000781	G-ænial Anterior, Unitip 20x0.16ml (0.28g), AE
++J022MD0032JX	003918	10000782	G-ænial Anterior, Unitip 20x0.16ml (0.28g), IE
++J022MD0032JX	003919	10000783	G-ænial Anterior, Unitip 10x0.16ml (0.28g), BW
++J022MD0032JX	003920	10000784	G-ænial Anterior, Unitip 10x0.16ml





			(0.28g), A4
++J022MD0032JX	003921	10000785	G-ænia Anterior, Unitip 10x0.16ml (0.28g), B2
++J022MD0032JX	003922	10000786	G-ænia Anterior, Unitip 10x0.16ml (0.28g), B3
++J022MD0032JX	003923	10000787	G-ænia Anterior, Unitip 10x0.16ml (0.28g), C3
++J022MD0032JX	003924	10000788	G-ænia Anterior, Unitip 10x0.16ml (0.28g), CVD
++J022MD0032JX	003925	10000789	G-ænia Anterior, Unitip 10x0.16ml (0.28g), AO2
++J022MD0032JX	003926	10000790	G-ænia Anterior, Unitip 10x0.16ml (0.28g), AO4
++J022MD0032JX	003927	10000791	G-ænia Anterior, Unitip 10x0.16ml (0.28g), JE
++J022MD0032JX	003928	10000792	G-ænia Anterior, Unitip 10x0.16ml (0.28g), TE
++J022MD0032JX	003929	10000793	G-ænia Anterior, Unitip 10x0.16ml (0.28g), SE
++J022MD0032JX	003930	10000794	G-ænia Anterior, Unitip 10x0.16ml (0.28g), CVE
++J022MD0032JX	003931	10000795	G-ænia Anterior, Unitip 10x0.16ml (0.28g), XBW
++J022MD0032JX	003932	10000796	G-ænia Anterior, Unitip 10x0.16ml (0.28g), B1
++J022MD0032JX	003933	10000797	G-ænia Posterior, Unitip 20x0.16ml (0.33g), P-A1
++J022MD0032JX	003934	10000798	G-ænia Posterior, Unitip 20x0.16ml (0.33g), P-A2
++J022MD0032JX	003935	10000799	G-ænia Posterior, Unitip 20x0.16ml (0.33g), P-A3
++J022MD0032JX	003936	10000800	G-ænia Posterior, Unitip 20x0.16ml (0.33g), P-A3.5
++J022MD0032JX	003937	10000801	G-ænia Posterior, Unitip 20x0.16ml (0.33g), P-JE
++J022MD0032JX	003938	10000802	G-ænia Posterior, Unitip 20x0.16ml (0.33g), P-IE
++J022MD0032JX	003939	10000803	G-ænia Anterior, Syringe 2.7ml (4.7g), BW
++J022MD0032JX	003940	10000804	G-ænia Anterior, Syringe 2.7ml (4.7g), A1
++J022MD0032JX	003941	10000805	G-ænia Anterior, Syringe 2.7ml (4.7g), A2
++J022MD0032JX	003942	10000806	G-ænia Anterior, Syringe 2.7ml (4.7g), A3
++J022MD0032JX	003943	10000807	G-ænia Anterior, Syringe 2.7ml (4.7g), A3.5
++J022MD0032JX	003944	10000808	G-ænia Anterior, Syringe 2.7ml (4.7g), A4
++J022MD0032JX	003945	10000809	G-ænia Anterior, Syringe 2.7ml (4.7g), B2
++J022MD0032JX	003946	10000810	G-ænia Anterior, Syringe 2.7ml (4.7g), B3
++J022MD0032JX	003947	10000811	G-ænia Anterior, Syringe 2.7ml (4.7g), C3
++J022MD0032JX	003948	10000812	G-ænia Anterior, Syringe 2.7ml (4.7g), CV
++J022MD0032JX	003949	10000813	G-ænia Anterior, Syringe 2.7ml (4.7g),





			CVD
++J022MD0032JX	003950	10000814	G-ænia Anterior, Syringe 2.7ml (4.7g), AO2
++J022MD0032JX	003951	10000815	G-ænia Anterior, Syringe 2.7ml (4.7g), AO3
++J022MD0032JX	003952	10000816	G-ænia Anterior, Syringe 2.7ml (4.7g), AO4
++J022MD0032JX	003953	10000817	G-ænia Anterior, Syringe 2.7ml (4.7g), JE
++J022MD0032JX	003954	10000818	G-ænia Anterior, Syringe 2.7ml (4.7g), AE
++J022MD0032JX	003955	10000819	G-ænia Anterior, Syringe 2.7ml (4.0g), TE
++J022MD0032JX	003956	10000820	G-ænia Anterior, Syringe 2.7ml (4.7g), IE
++J022MD0032JX	003957	10000821	G-ænia Anterior, Syringe 2.7ml (4.7g), SE
++J022MD0032JX	003958	10000822	G-ænia Anterior, Syringe 2.7ml (4.7g), CVE
++J022MD0032JX	003959	10000823	G-ænia Anterior, Syringe 2.7ml (4.7g), XBW
++J022MD0032JX	003960	10000824	G-ænia Anterior, Syringe 2.7ml (4.7g), B1
++J022MD0032JX	003961	10000825	G-ænia Posterior, Syringe 2.7ml (5.5g), P-A1
++J022MD0032JX	003962	10000826	G-ænia Posterior, Syringe 2.7ml (5.5g), P-A2
++J022MD0032JX	003963	10000827	G-ænia Posterior, Syringe 2.7ml (5.5g), P-A3
++J022MD0032JX	003964	10000828	G-ænia Posterior, Syringe 2.7ml (5.5g), P-A3.5
++J022MD0032JX	003965	10000829	G-ænia Posterior, Syringe 2.7ml (5.5g), P-JE
++J022MD0032JX	003966	10000830	G-ænia Posterior, Syringe 2.7ml (5.5g), P-IE
++J022MD0032JX	004649	10000936	G-ænia Anterior, Unitip 20x0.16ml (0.28g), A1
++J022MD0032JX	004650	10000937	G-ænia Anterior, Unitip 20x0.16ml (0.28g), A2
++J022MD0032JX	004651	10000938	G-ænia Anterior, Unitip 20x0.16ml (0.28g), A3
++J022MD0032JX	004652	10000939	G-ænia Anterior, Unitip 20x0.16ml (0.28g), A3.5
++J022MD0032JX	004653	10000940	G-ænia Anterior, Unitip 20x0.16ml (0.28g), AO3
++J022MD0032JX	004654	10000941	G-ænia Anterior, Unitip 20x0.16ml (0.28g), CV
++J022MD0032JX	004655	10000942	G-ænia Anterior, Unitip 20x0.16ml (0.28g), AE
++J022MD0032JX	004656	10000943	G-ænia Anterior, Unitip 20x0.16ml (0.28g), IE
++J022MD0032JX	004657	10000944	G-ænia Anterior, Unitip 10x0.16ml (0.28g), BW
++J022MD0032JX	004658	10000945	G-ænia Anterior, Unitip 10x0.16ml (0.28g), A4
++J022MD0032JX	004659	10000946	G-ænia Anterior, Unitip 10x0.16ml





			(0.28g), B2
++J022MD0032JX	004660	10000947	G-ænia Anterior, Unitip 10x0.16ml (0.28g), B3
++J022MD0032JX	004661	10000948	G-ænia Anterior, Unitip 10x0.16ml (0.28g), C3
++J022MD0032JX	004662	10000949	G-ænia Anterior, Unitip 10x0.16ml (0.28g), CVD
++J022MD0032JX	004663	10000950	G-ænia Anterior, Unitip 10x0.16ml (0.28g), AO2
++J022MD0032JX	004664	10000951	G-ænia Anterior, Unitip 10x0.16ml (0.28g), AO4
++J022MD0032JX	004665	10000952	G-ænia Anterior, Unitip 10x0.16ml (0.28g), JE
++J022MD0032JX	004666	10000953	G-ænia Anterior, Unitip 10x0.16ml (0.28g), TE
++J022MD0032JX	004667	10000954	G-ænia Anterior, Unitip 10x0.16ml (0.28g), SE
++J022MD0032JX	004668	10000955	G-ænia Anterior, Unitip 10x0.16ml (0.28g), CVE
++J022MD0032JX	004669	10000956	G-ænia Anterior, Unitip 10x0.16ml (0.28g), XBW
++J022MD0032JX	004670	10000957	G-ænia Anterior, Unitip 10x0.16ml (0.28g), B1
++J022MD0032JX	004671	10000958	G-ænia Posterior, Unitip 20x0.16ml (0.33g), P-A1
++J022MD0032JX	004672	10000959	G-ænia Posterior, Unitip 20x0.16ml (0.33g), P-A2
++J022MD0032JX	004673	10000960	G-ænia Posterior, Unitip 20x0.16ml (0.33g), P-A3
++J022MD0032JX	004674	10000961	G-ænia Posterior, Unitip 20x0.16ml (0.33g), P-A3.5
++J022MD0032JX	004675	10000962	G-ænia Posterior, Unitip 20x0.16ml (0.33g), P-JE
++J022MD0032JX	004676	10000963	G-ænia Posterior, Unitip 20x0.16ml (0.33g), P-IE
++J022MD0032JX	004677	10000964	G-ænia Anterior, Syringe 2.7ml (4.7g), BW
++J022MD0032JX	004678	10000965	G-ænia Anterior, Syringe 2.7ml (4.7g), A1
++J022MD0032JX	004679	10000966	G-ænia Anterior, Syringe 2.7ml (4.7g), A2
++J022MD0032JX	004680	10000967	G-ænia Anterior, Syringe 2.7ml (4.7g), A3
++J022MD0032JX	004681	10000968	G-ænia Anterior, Syringe 2.7ml (4.7g), A3.5
++J022MD0032JX	004682	10000969	G-ænia Anterior, Syringe 2.7ml (4.7g), A4
++J022MD0032JX	004683	10000970	G-ænia Anterior, Syringe 2.7ml (4.7g), B2
++J022MD0032JX	004684	10000971	G-ænia Anterior, Syringe 2.7ml (4.7g), B3
++J022MD0032JX	004685	10000972	G-ænia Anterior, Syringe 2.7ml (4.7g), C3
++J022MD0032JX	004686	10000973	G-ænia Anterior, Syringe 2.7ml (4.7g), CV
++J022MD0032JX	004687	10000974	G-ænia Anterior, Syringe 2.7ml (4.7g), CVD
++J022MD0032JX	004688	10000975	G-ænia Anterior, Syringe 2.7ml (4.7g),





			A02
++J022MD0032JX	004689	10000976	G-ænial Anterior, Syringe 2.7ml (4.7g), A03
++J022MD0032JX	004690	10000977	G-ænial Anterior, Syringe 2.7ml (4.7g), A04
++J022MD0032JX	004691	10000978	G-ænial Anterior, Syringe 2.7ml (4.7g), JE
++J022MD0032JX	004692	10000979	G-ænial Anterior, Syringe 2.7ml (4.7g), AE
++J022MD0032JX	004693	10000980	G-ænial Anterior, Syringe 2.7ml (4.0g), TE
++J022MD0032JX	004694	10000981	G-ænial Anterior, Syringe 2.7ml (4.7g), IE
++J022MD0032JX	004695	10000982	G-ænial Anterior, Syringe 2.7ml (4.7g), SE
++J022MD0032JX	004696	10000983	G-ænial Anterior, Syringe 2.7ml (4.7g), CVE
++J022MD0032JX	004697	10000984	G-ænial Anterior, Syringe 2.7ml (4.7g), XBW
++J022MD0032JX	004698	10000985	G-ænial Anterior, Syringe 2.7ml (4.7g), B1
++J022MD0032JX	004699	10000986	G-ænial Posterior, Syringe 2.7ml (5.5g), P-A1
++J022MD0032JX	004700	10000987	G-ænial Posterior, Syringe 2.7ml (5.5g), P-A2
++J022MD0032JX	004701	10000988	G-ænial Posterior, Syringe 2.7ml (5.5g), P-A3
++J022MD0032JX	004702	10000989	G-ænial Posterior, Syringe 2.7ml (5.5g), P-A3.5
++J022MD0032JX	004703	10000990	G-ænial Posterior, Syringe 2.7ml (5.5g), P-JE
++J022MD0032JX	004704	10000991	G-ænial Posterior, Syringe 2.7ml (5.5g), P-IE
++J022MD0032JX	900537	10003303	G-aenial Unitip IE-A02-A2-AE sample kit
++J022MD0032JX	900607	10003322	G-aenial Unitip A2-A3-PA3 sample kit
++J022MD0032JX	901418	10003655	G-ænial Syringe + G-Premio BOND Promo Pack
++J022MD0032JX	901419	10003656	G-ænial Unitip + G-Premio BOND Promo Pack
++J022MD0032JX	901611	10004947	G-ænial Anterior A2-A3 Syringe Promo Pack.
++J022MD0032JX	901612	10004951	G-ænial Posterior PA2-PA3 Syringe Promo Pack
++J022MD0032JX	901613	10004870	G-ænial Anterior A2-A3 Unitip Promo Pack
++J022MD0032JX	901614	10004875	G-ænial Posterior PA2-PA3 Unitip Promo Pack
++J022MD0032JX	900705	10003357	G-aenial Post Syringe + G- Premio Bond Promo pack
++J022MD0032JX	900670	10003337	G-aenial Unitips + G- Premio Bond Promo pack
++J022MD0032JX	900669	10003336	G-ænial Syringe + G-Premio BOND Promo Pack
++J022MD0032JX	901517	10003749	PROMO G-aenial Posterior P-A3 Unitip
++J022MD0032JX	901516	10003748	PROMO G-aenial Posterior P-A2 Unitip
++J022MD0032JX	901515	10003747	PROMO G-aenial Anterior A3 Unitip





++J022MD0032JX	901514	10003746	PROMO G-aenial Anterior A2 Unitip
++J022MD0032JX	901513	10003745	PROMO G-aenial Posterior P-A3 Syringe
++J022MD0032JX	901512	10003744	PROMO G-aenial Posterior P-A2 Syringe
++J022MD0032JX	901511	10003743	PROMO G-aenial Anterior A3 Syringe
++J022MD0032JX	901510	10003742	PROMO G-aenial Anterior A2 Syringe