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, uznemoties 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**	GRADIA™ PLUS

Ime Izdelka **Ürün Adı**	
Verwendungszweck **Intended Purpose** **Usage prévu** **Uso inteso** **Izmantošanas mērķis** **Finalidade prevista** **Predvideni Namen** **Hedeflenen Amaç**	Modular Composite System For Indirect Restorations
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**	++J022MD0162KD

UDI-DI base **UDI-DI bāze** **UDI-DI básico** **Osnovni UDI-DI** **Temel UDI-DI**	

-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 sekojosīem 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 beyanın ilgili olduğu aşağıdaki standartlara veya diğer normatif belgelere uygundur:

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

-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 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
++J022MD0162KD	901048	10003559	GRADIA PLUS Layer Set 5x GRADIA PLUS Opaque 2.0ml O-Base, OA, OB, OC, OD, 14x GRADIA PLUS Paste Heavy Body 3.3ml HB-DA1, HB-DA2, HB-DA3, HB-DA3.5, HB-DB1, HB-DB3, HB-DC3, HB-DD2, HB-EL, HB-ED, HB-CLF, HB-PE, HB-ODA, HB-ODB, 5x GRADIA PLUS Dispensing Tip Needle Tip & Light Protective Cover, 1x Mixing Pad N° 22, 1x Plastic Spatula N° 2 Blue
++J022MD0162KD	901050	10003560	GRADIA PLUS Paint Set 10x GRADIA PLUS Lustre Paint 0.8ml LP-A, LP-B, LP-C, LP-D, LP-CLF, LP-CL, LP-Blue, LP-Grey, LP-Cream, LP-Lavender, 1x GRADIA PLUS Lustre Paint Diluting Liquid 3ml, 10x GRADIA PLUS Dispensing Tip Needle Type Small & Light Protective Cover, 10x Brush Round N° 1, 10x Brush Flat N° 1, 2x Brush Holder (Ivory & White), 5x Disposable Palette, 1x Mixing Pad N° 14B
++J022MD0162KD	901051	10003561	GRADIA PLUS Gum Shade Set 1x GRADIA PLUS Opaque 2.0ml O-Base, 2x GRADIA PLUS Gum Shades Opaque 2.0ml GO-1, GO-2, 1x GRADIA PLUS Lustre Paint 0.8ml LP-CL, 2x GRADIA PLUS Gum Shades Lustre Paint 0.8ml GLP-Bright Red, GLP-Violet, 4x GRADIA PLUS Gum Shades Light Body 2.0ml GLB-1, GLB-2, GLB-3, GLB-CL, 1x GRADIA PLUS Gum Shades Heavy Body 3.3ml GHB-2, 1x GRADIA PLUS Lustre Paint Diluting Liquid 3ml, 10x GRADIA PLUS Mixotip, 5x GRADIA PLUS Dispensing Tip Plastic Type Wide & Light Protective Cover, 5x GRADIA PLUS

			Dispensing Tip Needle Type Small & Light Protective Cover, 5x GRADIA PLUS Dispensing Tip Needle Tip & Light Protective Cover, 10x Brush Round N° 1, 10x Brush Flat N° 1, 2x Brush Holder (Ivory & White), 5x Disposable Palette, 1x Mixing Pad N° 22, 1x Plastic Spatula N° 2 Blue
++J022MD0162KD	901052	10003562	GRADIA PLUS One Body Set 5x GRADIA PLUS Opaque 2.0ml O-Base, OA, OB, OC, OD, 1x GRADIA PLUS Paste Light Body 2.0ml LB-Base OD, 5x GRADIA PLUS One Body 2.0ml LB-A, LB-B, LB-C, LB-D, LB-W, 10x GRADIA PLUS Dispensing Tip Plastic Type Wide & Light Protective Cover, 5x GRADIA PLUS Dispensing Tip Needle Tip & Light Protective Cover, 1x Mixing Pad N° 22, 1x Plastic Spatula N° 2 Blue
++J022MD0162KD	901053	10003563	GRADIA PLUS Accessory Set 1x GRADIA PLUS Air Barrier 10ml, 1x GRADIA PLUS Separator 5ml, 1x GRADIA PLUS Die Hardner 5ml, 1x GRADIA PLUS Modelling Liquid 3ml, 1x Ceramic Primer II 3ml, 1x Metalprimer Z 5ml, 1x Acrylic Primer 5ml, 1x Diapolisher Paste 2g, 10x Brush Round N° 1, 10x Brush Flat N° 1 , 2x Brush Holder (Ivory & White), 1x Brush N° 7, 1x Shade Guide Kit, 1x Mixing Pad N° 22
++J022MD0162KD	901054	10003564	GRADIA PLUS Opaque O-Base, 2.0ml, 1pc
++J022MD0162KD	901055	10003565	GRADIA PLUS Opaque OA, 2.0ml, 1pc
++J022MD0162KD	901056	10003566	GRADIA PLUS Opaque OB, 2.0ml, 1pc
++J022MD0162KD	901057	10003567	GRADIA PLUS Opaque OC, 2.0ml, 1pc
++J022MD0162KD	901058	10003568	GRADIA PLUS Opaque OD, 2.0ml, 1pc
++J022MD0162KD	901059	10003569	GRADIA PLUS Opaque OA1, 2.0ml, 1pc
++J022MD0162KD	901067	10003577	GRADIA PLUS Opaque GO-1, 2.0ml, 1pc
++J022MD0162KD	901068	10003578	GRADIA PLUS Opaque GO-2, 2.0ml, 1pc
++J022MD0162KD	901069	10003579	GRADIA PLUS Paste HB-DA1, 3.3ml, 1pc
++J022MD0162KD	901070	10003580	GRADIA PLUS Paste HB-DA2, 3.3ml, 1pc
++J022MD0162KD	901071	10003581	GRADIA PLUS Paste HB-DA3, 3.3ml, 1pc
++J022MD0162KD	901072	10003582	GRADIA PLUS Paste HB-DA3.5, 3.3ml, 1pc
++J022MD0162KD	901073	10003583	GRADIA PLUS Paste HB-DB1, 3.3ml, 1pc
++J022MD0162KD	901074	10003584	GRADIA PLUS Paste HB-DB3, 3.3ml, 1pc
++J022MD0162KD	901075	10003585	GRADIA PLUS Paste HB-DC3, 3.3ml, 1pc
++J022MD0162KD	901076	10003586	GRADIA PLUS Paste HB-DD2, 3.3ml, 1pc
++J022MD0162KD	901077	10003587	GRADIA PLUS Paste HB-EL, 3.3ml, 1pc
++J022MD0162KD	901078	10003588	GRADIA PLUS Paste HB-ED, 3.3ml, 1pc
++J022MD0162KD	901079	10003589	GRADIA PLUS Paste HB-CLF, 3.3ml, 1pc
++J022MD0162KD	901080	10003590	GRADIA PLUS Paste HB-PE, 3.3ml, 1pc
++J022MD0162KD	901081	10003591	GRADIA PLUS Paste HB-ODA, 3.3ml, 1pc
++J022MD0162KD	901082	10003592	GRADIA PLUS Paste HB-ODB, 3.3ml, 1pc
++J022MD0162KD	901083	10003593	GRADIA PLUS Paste HB-ODC, 3.3ml, 1pc
++J022MD0162KD	901084	10003594	GRADIA PLUS Paste HB-ODD, 3.3ml, 1pc
++J022MD0162KD	901085	10003595	GRADIA PLUS Paste HB-ODW, 3.3ml, 1pc
++J022MD0162KD	901086	10003596	GRADIA PLUS Paste HB-DW, 3.3ml, 1pc
++J022MD0162KD	901087	10003597	GRADIA PLUS Paste GHB-1, 3.3ml, 1pc
++J022MD0162KD	901088	10003598	GRADIA PLUS Paste GHB-2, 3.3ml, 1pc
++J022MD0162KD	901089	10003599	GRADIA PLUS Paste GHB-3, 3.3ml, 1pc
++J022MD0162KD	901090	10003600	GRADIA PLUS Paste GHB-CL, 3.3ml, 1pc
++J022MD0162KD	901091	10003601	GRADIA PLUS Paste LB-Base E, 2ml, 1pc
++J022MD0162KD	901092	10003602	GRADIA PLUS Paste LB-Base CLF, 2ml, 1pc

++J022MD0162KD	901093	10003603	GRADIA PLUS Paste LB-Base D, 2ml, 1pc
++J022MD0162KD	901094	10003604	GRADIA PLUS Paste LB-DW, 2ml, 1pc
++J022MD0162KD	901095	10003605	GRADIA PLUS Paste LB-Base OD, 2ml, 1pc
++J022MD0162KD	901096	10003606	GRADIA PLUS Paste LB-ODW, 2ml, 1pc
++J022MD0162KD	901097	10003607	GRADIA PLUS Paste LB-Base Opal, 2ml, 1pc
++J022MD0162KD	901098	10003608	GRADIA PLUS Paste LB-Orange, 2ml, 1pc
++J022MD0162KD	901099	10003609	GRADIA PLUS Paste LB-Yellow, 2ml, 1pc
++J022MD0162KD	901100	10003610	GRADIA PLUS Paste LB-Red, 2ml, 1pc
++J022MD0162KD	901101	10003611	GRADIA PLUS Paste LB-Grey, 2ml, 1pc
++J022MD0162KD	901102	10003612	GRADIA PLUS Paste LB-Blue, 2ml, 1pc
++J022MD0162KD	901103	10003613	GRADIA PLUS Paste LB-Milky, 2ml, 1pc
++J022MD0162KD	901104	10003614	GRADIA PLUS Paste LB-Inlay E, 2ml, 1pc
++J022MD0162KD	901105	10003615	GRADIA PLUS Paste LB-Inlay TD, 2ml, 1pc
++J022MD0162KD	901106	10003616	GRADIA PLUS ONE BODY LB-A, 2.0ml, 1pc
++J022MD0162KD	901107	10003617	GRADIA PLUS ONE BODY LB-B, 2.0ml, 1pc
++J022MD0162KD	901108	10003618	GRADIA PLUS ONE BODY LB-C, 2.0ml, 1pc
++J022MD0162KD	901109	10003619	GRADIA PLUS ONE BODY LB-D, 2.0ml, 1pc
++J022MD0162KD	901110	10003620	GRADIA PLUS ONE BODY LB-W, 2.0ml, 1pc
++J022MD0162KD	901111	10003621	GRADIA PLUS Paste GLB-1, 2ml, 1pc
++J022MD0162KD	901112	10003622	GRADIA PLUS Paste GLB-2, 2ml, 1pc
++J022MD0162KD	901113	10003623	GRADIA PLUS Paste GLB-3, 2ml, 1pc
++J022MD0162KD	901114	10003624	GRADIA PLUS Paste GLB-CL, 2ml, 1pc
++J022MD0162KD	901115	10003625	GRADIA PLUS LP-A, 0.8ml, 1pc
++J022MD0162KD	901116	10003626	GRADIA PLUS LP-B, 0.8ml, 1pc
++J022MD0162KD	901117	10003627	GRADIA PLUS LP-C, 0.8ml, 1pc
++J022MD0162KD	901118	10003628	GRADIA PLUS LP-D, 0.8ml, 1pc
++J022MD0162KD	901119	10003629	GRADIA PLUS LP-CLF, 0.8ml, 1pc
++J022MD0162KD	901120	10003630	GRADIA PLUS LP-Blue, 0.8ml, 1pc
++J022MD0162KD	901121	10003631	GRADIA PLUS LP-Grey, 0.8ml, 1pc
++J022MD0162KD	901122	10003632	GRADIA PLUS LP-Cream, 0.8ml, 1pc
++J022MD0162KD	901123	10003633	GRADIA PLUS LP-Lavender, 0.8ml, 1pc
++J022MD0162KD	901124	10003634	GRADIA PLUS LP-CL, 0.8ml, 1pc
++J022MD0162KD	901125	10003635	GRADIA PLUS GLP-Bright Red, 0.8ml, 1pc
++J022MD0162KD	901126	10003636	GRADIA PLUS GLP-Violet, 0.8ml, 1pc
++J022MD0162KD	901127	10003637	GRADIA PLUS LP Diluting Liquid, 3ml, 1pc
++J022MD0162KD	901129	10003639	GRADIA PLUS Modelling Liquid, 3ml, 1pc
++J022MD0162KD	901409	10003652	GRADIA PLUS Layer Pro Set 4x GRADIA PLUS Paste Heavy Body 3.3ml HB-ODC, HB-ODD, HB-ODW, HB-DW, 16x GRADIA PLUS Paste Light Body 2.0ml LB-Base E, LB-Base CLF, LB-Base D, LB-DW, LB-Base OD, LB-ODW, LB-Base Opal, LB-Orange, LB-Yellow, LB-Red, LB-Grey, LB-Blue, LB-Milky, LB-Inlay E, LB-Inlay TD, 10x GRADIA PLUS Mixotip, 15x GRADIA PLUS Dispensing Tip Plastic Type Wide & Light Protective Cover, 1x Mixing Pad N° 22, 1x Plastic Spatula N° 2 Blue
++J022MD0162KD	/	10007537	GRADIA PLUS Paste HB-DA4, 3.3ml, 1pc
++J022MD0162KD	/	10007538	GRADIA PLUS Paste HB-DB2, 3.3ml, 1pc
++J022MD0162KD	/	10007539	GRADIA PLUS Paste HB-DB4, 3.3ml, 1pc
++J022MD0162KD	/	10007540	GRADIA PLUS Paste HB-DC1, 3.3ml, 1pc
++J022MD0162KD	/	10007541	GRADIA PLUS Paste HB-DC2, 3.3ml, 1pc
++J022MD0162KD	/	10007542	GRADIA PLUS Paste HB-DC4, 3.3ml, 1pc
++J022MD0162KD	/	10007543	GRADIA PLUS Paste HB-DD3, 3.3ml, 1pc
++J022MD0162KD	/	10007544	GRADIA PLUS Paste HB-DD4, 3.3ml, 1pc

++J022MD0162KD	/	10007545	GRADIA PLUS Paste LB-DA1, 2ml, 1pc
++J022MD0162KD	/	10007546	GRADIA PLUS Paste LB-DA2, 2ml, 1pc
++J022MD0162KD	/	10007547	GRADIA PLUS Paste LB-DA3, 2ml, 1pc
++J022MD0162KD	/	10007548	GRADIA PLUS Paste LB-DA3.5, 2ml, 1pc
++J022MD0162KD	/	10007549	GRADIA PLUS Paste LB-DB1, 2ml, 1pc
++J022MD0162KD	/	10007550	GRADIA PLUS Paste LB-DB3, 2ml, 1pc
++J022MD0162KD	/	10007551	GRADIA PLUS Paste LB-DC2, 2ml, 1pc
++J022MD0162KD	/	10007552	GRADIA PLUS Paste LB-DD3, 2ml, 1pc
++J022MD0162KD	/	10007553	GRADIA PLUS Paste LB-EL, 2ml, 1pc
++J022MD0162KD	/	10007554	GRADIA PLUS Paste LB-ED, 2ml, 1pc