



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	Gradia Direct Flo Gradia Direct LoFlo
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Ürün Adı	
Verwendungszweck Intended Purpose Usage prévu Uso inteso Izmantošanas mērķis Finalidade prevista Predvideni Namen Hedeflenen Amaç	Light-cured flowable composite
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	++J022MD0071K9





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

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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
++J022MD0071K9	002278	10000355	GRADIA Direct Flo, Syringe 2x0.8ml (1.3g), A1 + 4x Dispensing Tip (needle type), 2x Light Protective Cover
++J022MD0071K9	002279	10000356	GRADIA Direct Flo, Syringe 2x0.8ml (1.3g), A2 + 4x Dispensing Tip (needle type), 2x Light Protective Cover
++J022MD0071K9	002280	10000357	GRADIA Direct Flo, Syringe 2x0.8ml (1.3g), A3 + 4x Dispensing Tip (needle type), 2x Light Protective Cover
++J022MD0071K9	002281	10000358	GRADIA Direct Flo, Syringe 2x0.8ml (1.3g), A3.5 + 4x Dispensing Tip (needle type), 2x Light Protective Cover
++J022MD0071K9	002284	10000359	GRADIA Direct Flo, Syringe 2x0.8ml (1.3g), AO3 + 4x Dispensing Tip (needle type), 2x Light Protective Cover
++J022MD0071K9	002358	10000369	GRADIA Direct Flo, Syringe 2x0.8ml (1.3g), BW + 4x Dispensing Tip (needle type), 2x Light Protective Cover
++J022MD0071K9	002285	10000360	GRADIA Direct Flo, Syringe 2x0.8ml (1.3g), CV + 4x Dispensing Tip (needle type), 2x Light Protective Cover
++J022MD0071K9	003441	10000676	GRADIA Direct Flo, Syringe 2x0.8ml (1.3g), A1 + 4x Dispensing Tip (needle type), 2x Light Protective Cover
++J022MD0071K9	003442	10000677	GRADIA Direct Flo, Syringe 2x0.8ml (1.3g), A2





			+ 4x Dispensing Tip (needle type), 2x Light Protective Cover
++J022MD0071K9	003443	10000678	GRADIA Direct Flo, Syringe 2x0.8ml (1.3g), A3 + 4x Dispensing Tip (needle type), 2x Light Protective Cover
++J022MD0071K9	003444	10000679	GRADIA Direct Flo, Syringe 2x0.8ml (1.3g), A3.5 + 4x Dispensing Tip (needle type), 2x Light Protective Cover
++J022MD0071K9	003445	10000680	GRADIA Direct Flo, Syringe 2x0.8ml (1.3g), AO3 + 4x Dispensing Tip (needle type), 2x Light Protective Cover
++J022MD0071K9	003447	10000682	GRADIA Direct Flo, Syringe 2x0.8ml (1.3g), BW + 4x Dispensing Tip (needle type), 2x Light Protective Cover
++J022MD0071K9	003446	10000681	GRADIA Direct Flo, Syringe 2x0.8ml (1.3g), CV + 4x Dispensing Tip (needle type), 2x Light Protective Cover
++J022MD0071K9	002289	10000361	GRADIA Direct LoFlo, Syringe 2x0.8ml (1.3g), A1 + 4x Dispensing Tip (needle type), 2x Light Protective Cover
++J022MD0071K9	002290	10000362	GRADIA Direct LoFlo, Syringe 2x0.8ml (1.3g), A2 + 4x Dispensing Tip (needle type), 2x Light Protective Cover
++J022MD0071K9	002291	10000363	GRADIA Direct LoFlo, Syringe 2x0.8ml (1.3g), A3 + 4x Dispensing Tip (needle type), 2x Light Protective Cover
++J022MD0071K9	002292	10000364	GRADIA Direct LoFlo, Syringe 2x0.8ml (1.3g), A3.5 + 4x Dispensing Tip (needle type), 2x Light Protective Cover
++J022MD0071K9	002295	10000365	GRADIA Direct LoFlo, Syringe 2x0.8ml (1.3g), AO3 + 4x Dispensing Tip (needle type), 2x Light Protective Cover
++J022MD0071K9	002298	10000367	GRADIA Direct LoFlo, Syringe 2x0.8ml (1.3g), BW + 4x Dispensing Tip (needle type), 2x Light Protective Cover
++J022MD0071K9	002296	10000366	GRADIA Direct LoFlo, Syringe 2x0.8ml (1.3g), CV + 4x Dispensing Tip (needle type), 2x Light Protective Cover
++J022MD0071K9	003448	10000683	GRADIA Direct LoFlo, Syringe





			2x0.8ml (1.3g), A1 + 4x Dispensing Tip (needle type), 2x Light Protective Cover
++J022MD0071K9	003449	10000684	GRADIA Direct LoFlo, Syringe 2x0.8ml (1.3g), A2 + 4x Dispensing Tip (needle type), 2x Light Protective Cover
++J022MD0071K9	003450	10000685	GRADIA Direct LoFlo, Syringe 2x0.8ml (1.3g), A3 + 4x Dispensing Tip (needle type), 2x Light Protective Cover
++J022MD0071K9	003451	10000686	GRADIA Direct LoFlo, Syringe 2x0.8ml (1.3g), A3.5 + 4x Dispensing Tip (needle type), 2x Light Protective Cover
++J022MD0071K9	003452	10000687	GRADIA Direct LoFlo, Syringe 2x0.8ml (1.3g), AO3 + 4x Dispensing Tip (needle type), 2x Light Protective Cover
++J022MD0071K9	003454	10000689	GRADIA Direct LoFlo, Syringe 2x0.8ml (1.3g), BW + 4x Dispensing Tip (needle type), 2x Light Protective Cover
++J022MD0071K9	003453	10000688	GRADIA Direct LoFlo, Syringe 2x0.8ml (1.3g), CV + 4x Dispensing Tip (needle type), 2x Light Protective Cover