



**EU-KONFORMITÄTSEKTLÄRUNG**  
**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:

<b>Produktname</b>	GC Modeling Liquid
<b>Product Name</b>	
<b>Nom du produit</b>	
<b>Nome del prodotto</b>	
<b>Produkta nosaukums</b>	
<b>Nome do produto</b>	





<b>Ime Izdelka</b> <b>Ürün Adı</b>	
<b>Verwendungszweck</b> <b>Intended Purpose</b> <b>Usage prévu</b> <b>Usò inteso</b> <b>Izmantošanas mērķis</b> <b>Finalidade prevista</b> <b>Predvideni Namen</b> <b>Hedeflenen Amaç</b>	Liquid To Model Composite Materials For Direct Restorations
<b>Klassifizierung gemäß Anhang VIII der Verordnung (EU) 2017/745</b> <b>Classification according to Annex VIII of the Regulation (EU) 2017/745</b> <b>Classification selon l'Annexe VIII du Règlement (UE) 2017/745</b> <b>Classificazione secondo l'Allegato VIII del Regolamento 2017/745</b> <b>Klasifikācija saskaņā ar regulas (EU) 2017/745 pielikumu VIII</b> <b>Classificação de acordo com o Anexo VIII do Regulamento (UE) 2017/745</b> <b>Razred tveganja v skladu s Prilogo VIII k Uredbi (EU) 2017/745</b> <b>(AB) 2017/745 sayılı Tüzüğün Ek VIII'ine göre sınıflandırma</b>	Klasse; Class; Classe; Classe; Klase; Classe; Razred tveganja; Sınıf IIa Regel; Rule; Règle; Regola; Likums; Regra; Pravilo; Kural 8, 19
<b>Artikelliste</b> <b>Article List</b> <b>Liste des articles</b> <b>Lista degli Articoli</b> <b>Artikulu saraksts</b> <b>Lista de Artigos</b> <b>Seznam kod izdelkov</b> <b>Makale Listesi</b>	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
<b>Basis-UDI-DI</b> <b>Basic UDI-DI</b> <b>IUD-ID de base</b>	++J022MD0143K9



<b>UDI-DI base</b> <b>UDI-DI bāze</b> <b>UDI-DI básico</b> <b>Osnovni UDI-DI</b> <b>Temel UDI-DI</b>	
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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 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 karşilar 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; Certificat; 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**

<b>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</b>	<b>Artikel- Code Article Code Code article Codice Articolo Artikuls Código do artigo Koda Izdelka Madde Kodu</b>	<b>Neuer Artikel-Code New Article code Nouveau code article Nuovo Codice articolo Jaunais artikuls Novo código do artigo Nova Koda Izdelka Yeni Makale kodu</b>	<b>Beschreibung Description Description Descrizione Apraksts Descrição Opis Açıklama</b>
++J022MD0143K9	900743	10003387	GC Composite Modelling Kit 1x GC Modelling Liquid 6ml, 2x Gradia Brush Holder, 5x Gradia Brush Flat, 5x Gradia Brush Round, 1x Mixing pad
++J022MD0143K9	012243	10001380	GC Modelling Liquid, Refill 6ml
++J022MD0143K9	900744	10003388	GC Composite Modelling Kit 1x GC Modelling Liquid 6ml, 2x Gradia Brush Holder, 5x Gradia Brush Flat, 5x Gradia Brush Round, 1x Mixing pad
++J022MD0143K9	012244	10001381	GC Modelling Liquid, Refill 6ml