**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:

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|---|---|
| **Produktname**<br>**Product Name**<br>**Nom du produit**<br>**Nome del prodotto**<br>**Produkta nosaukums**<br>**Nome do produto**<br>**Ime Izdelka** | GC FujiCEM Evolve |

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| **Ürün Adı** | |
| **Verwendungszweck**<br>**Intended Purpose**<br>**Usage prévu**<br>**Uso inteso**<br>**Izmantošanas mērķis**<br>**Finalidade prevista**<br>**Predvideni Namen**<br>**Hedeflenen Amaç** | Radiopaque resin reinforced glass ionomer luting cement |
| **Klassifizierung gemäß Anhang VIII der Verordnung (EU) 2017/745**<br>**Classification according to Annex VIII of the Regulation (EU) 2017/745**<br>**Classification selon l'Annexe VIII du Règlement (UE) 2017/745**<br>**Classificazione secondo l'Allegato VIII del Regolamento 2017/745**<br>**Klasifikācija saskaņā ar regulas (EU) 2017/745 pielikumu VIII**<br>**Classificação de acordo com o Anexo VIII do Regulamento (UE) 2017/745**<br>**Razred tveganja v skladu s Prilogo VIII k Uredbi (EU) 2017/745**<br>**(AB) 2017/745 sayılı Tüzüğün Ek VIII'ine göre sınıflandırma** | Klasse; Class; Classe; Classe; Klase; Classe; Razred tveganja; Sınıf<br>IIa<br>Regel; Rule; Règle; Regola; Likums; Regra; Pravilo; Kural<br>8, 19 |
| **Artikelliste**<br>**Article List**<br>**Liste des articles**<br>**Lista degli Articoli**<br>**Artikulu saraksts**<br>**Lista de Artigos**<br>**Seznam kod izdelkov**<br>**Makale Listesi** | Gemäß Anhang<br>According to the Attachment<br>Conformément à la pièce jointe<br>Secondo l'Allegato<br>Saskaņā ar pielikumu<br>De acordo com o Anexo<br>V skladu s Prilogo<br>Ek'e göre |
| **Basis-UDI-DI**<br>**Basic UDI-DI**<br>**IUD-ID de base**<br>**UDI-DI base**<br>**UDI-DI bāze** | ++J022MD0146KF |

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| **UDI-DI básico**<br>**Osnovni UDI-DI**<br>**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:

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| EN ISO 13485:2016 | Medical devices - Quality management systems - Requirements for regulatory purposes |
| ISO 9917-2:2017 | Dentistry -Water-based cements –Part 2: Resin-modified cements |

-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<br>Basic UDI-DI<br>IUD-ID de base<br>UDI-DI base<br>UDI-DI bāze<br>UDI-DI básico<br>Osnovni UDI-DI<br>Temel UDI-DI | Artikel-Code<br>Article Code<br>Code article<br>Codice Articolo<br>Artikuls<br>Código do artigo<br>Koda Izdelka<br>Madde Kodu | Neuer Artikel-Code<br>New Article code<br>Nouveau code article<br>Nuovo Codice articolo<br>Jaunais artikuls<br>Novo código do artigo<br>Nova Koda Izdelka<br>Yeni Makale kodu | Beschreibung<br>Description<br>Description<br>Descrizione<br>Apraksts<br>Descrição<br>Opis<br>Açıklama |
|---|---|---|---|
| ++J022MD0146KF | 012950 | 10004928 | GC FujiCEM Evolve Triple Pack Automix 3 x GC FujiCEM Evolve syringe (9.2 g / 5.0 ml) + 45x GC Push and Click Tip Regular |
| ++J022MD0146KF | 012949 | 10004916 | GC FujiCEM Evolve Triple Pack Handmix 3 x GC FujiCEM Evolve syringe (9.2 g / 5.0 ml) + 1x Mixing Pad #22 |
| ++J022MD0146KF | 013584 | 10006621 | GC FujiCEM Evolve Clinic Pack<br>8x GC FujiCEM Evolve syringe (9.2 g / 5.0 ml) & 2x Mixing Pad #22 |
| ++J022MD0146KF | 012948 | 10004926 | GC FujiCEM Evolve Single Pack<br>1x GC FujiCEM Evolve syringe (9.2 g / 5.0 ml) & 15 x GC Push and Click Tip Regular |
| ++J022MD0146KF | 012953 | 10004930 | GC FujiCEM Evolve Triple Pack Automix 3 x GC FujiCEM Evolve syringe (9.2 g / 5.0 ml)+ 45x GC Push and Click Tip Regular |

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| ++J022MD0146KF | 012952 | 10004871 | GC FujiCEM Evolve Triple Pack Handmix 3 x GC FujiCEM Evolve syringe (9.2 g / 5.0 ml)+ 1x Mixing Pad #22 |
| ++J022MD0146KF | 012951 | 10004927 | GC FujiCEM Evolve Single Pack 1x GC FujiCEM Evolve syringe (9.2 g / 5.0 ml) & 15 x GC Push and Click Tip Regular |
| ++J022MD0146KF | 901609 | 10004925 | GC FujiCEM Evolve Triple pack + Mixing tips FujiCEM Evolve Triple Pack Handmix (3 syringes, 5.0 ml/9.2 g) Push and Click Tip Regular (x15) mixing tips |
| ++J022MD0146KF | 901610 | 10004832 | GC FujiCEM Evolve Triple pack + Mixing tips FujiCEM Evolve Triple Pack Handmix (3 syringes, 5.0 ml/9.2 g) Push and Click Tip Regular (x15) mixing tips |