



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:

Produktname Product Name Nom du produit Nome del prodotto Produkta nosaukums Nome do produto Ime Izdelka Ürün Adı	GC Fuji PLUS GC Fuji PLUS CAPSULE GC Fuji PLUS EWT
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Verwendungszweck Intended Purpose Usage prévu Uso inteso Izmantošanas mērķis Finalidade prevista Predvideni Namen Hedeflenen Amaç	Radiopaque reinforced glass ionomer luting cement
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; Klasse; Classe; Razred tveganja; Sınıf Ila Regel; Rule; Règle; Regola; Likums; Regra; Pravilo; Kural 8
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 UDI-DI básico Osnovni UDI-DI Temel UDI-DI	++J022MD0060K4
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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
ISO 9917-2: 2017	Dentistry – Water-based cements – Part 2: Resin-modified cements
EN 1641:2009	Dentistry - Medical devices for dentistry – 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; Certificat; Sertifika

MDR 778483

Leuven, 12/02/2026.....

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
++J022MD0060K4	000219	10000084	Fuji Plus powder 15g
++J022MD0060K4	000220	10000085	Fuji Plus liquid 7ml
++J022MD0060K4	000222	10000087	GC Fuji PLUS, 50 Capsules, Yellow (Content: Box with 50 Capsules, with 0.36g Powder and 0.18g (0.16ml) Liquid each, Mixed Volume per Capsule 0.19ml)
++J022MD0060K4	000231	10000088	Fuji Plus EWT powder 15g A3
++J022MD0060K4	001409	10000157	GC Fuji PLUS, Intro Package, Full Set, A3 (Content: 15g Powder, 7ml Liquid, 6.5ml conditioner & Accessories)
++J022MD0060K4	001410	10000158	Fuji Plus powder Translucent 1
++J022MD0060K4	001411	10000159	Fuji Plus powder A3 15g
++J022MD0060K4	001418	10000161	Fuji Plus box of 50 caps A3 (Content: Box with 50 Capsules, with 0.36g Powder and 0.18g (0.16ml) Liquid each, Mixed Volume per Capsule 0.19ml)
++J022MD0060K4	003209	10000508	Fuji Plus box of 50 caps EEP (Content: Box with 50 Capsules, with 0.36g Powder and





			0.18g (0.16ml) Liquid each, Mixed Volume per Capsule 0.19ml)
++J022MD0060K4	003210	10000509	Fuji Plus box of 50 caps A3 EEP (Content: Box with 50 Capsules, with 0.36g Powder and 0.18g (0.16ml) Liquid each, Mixed Volume per Capsule 0.19ml)
++J022MD0060K4	003211	10000510	GC Fuji PLUS, Intro Package, Full Set, A3 EEP (Content: 15g Powder, 7ml Liquid, 6.5ml conditioner & Accessories)
++J022MD0060K4	003212	10000511	Fuji Plus powder Yellow 15g EEP
++J022MD0060K4	003213	10000512	Fuji Plus powder A3 15g EEP
++J022MD0060K4	003214	10000513	Fuji Plus powder Translucent 1
++J022MD0060K4	003215	10000514	Fuji Plus liquid 7ml EEP
++J022MD0060K4	003231	10000521	Fuji Plus EWT powder 15g A3 EE
++J022MD0060K4	800126	10001808	GC Fuji Plus Capsule promo
++J022MD0060K4	901519	10003751	PROMO Fuji Plus Caps A3 + Freegenol WEP
++J022MD0060K4	901520	10003752	PROMO Fuji Plus Caps A3 + Freegenol EEP
++J022MD0060K4	900508	10003295	Fuji Plus Capsule A3 promo 50+10 EEP
++J022MD0060K4	900507	10003294	GC Fuji Plus Capsule promo 50+10 EEP
++J022MD0060K4	800127	10001809	Fuji Plus Capsule A3 promo

