



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	GC Fuji IX GP
Nome del prodotto	GC Fuji IX GP CAPSULE
Produkta nosaukums	GC Fuji IX GP FAST
Nome do produto	GC Fuji IX GP EXTRA (Caps)
Ime izdelka	





Ürün Adı	
Verwendungszweck Intended Purpose Usage prévu Uso inteso Izmantošanas mērķis Finalidade prevista Predvideni Namen Hedeflenen Amaç	Radiopaque posterior glass ionomer restorative 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 IIa 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	++J022MD0064KC



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 beyanın ilgili olduğu aşağıdaki standartlara veya diğer normatif belgelere uygundur:

EN ISO 13485:2016 Medical Devices - Quality Management Systems - Requirements for Regulatory Purposes

ISO 9917-1:2007– Dentistry – Water-based cements, Part 1: Powder/liquid acid-base 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, 12/02/2026

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. adina



**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
++J022MD0064KC	000153	10000045	GC Fuji IX GP 1-1 pkg A3
++J022MD0064KC	000158	10000046	GC Fuji IX GP powder 15g A2
++J022MD0064KC	000159	10000047	GC Fuji IX GP powder 15g A3
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++J022MD0064KC	000162	10000050	GC Fuji IX GP powder 15g B3
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++J022MD0064KC	000215	10000081	GC Fuji IX GP Fast box of 50 caps B2
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			box of 50 caps A3.5 EEP
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			caps A3 EEP
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++J022MD0064KC	005078	10001034	GC Fuji IX GP EXTRA Powder 15g A1
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++J022MD0064KC	005081	10001037	GC Fuji IX GP EXTRA Powder 15g A3.5
++J022MD0064KC	005082	10004948	GC Fuji IX GP EXTRA Powder 15g B1
++J022MD0064KC	005083	10001038	GC Fuji IX GP EXTRA Powder 15g B2
++J022MD0064KC	005084	10001039	GC Fuji IX GP EXTRA Powder 15g B3
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			EXTRA Powder 15g C4
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++J022MD0064KC	005089	10001044	GC Fuji IX GP EXTRA Powder 15g A3.5 EEP
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