



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	G-aenial Universal Injectable
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Ürün Adı	
Verwendungszweck Intended Purpose Usage prévu Usò inteso Izmantošanas mērķis Finalidade prevista Predvideni Namen Hedeflenen Amaç	Universal light-cured radiopaque injectable 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	++J022MD0142K7



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 olduđu ařađıdaki standartlara veya diđer 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 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

.....
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
++J022MD0142K7	901471	10003703	G-æniel Universal Injectable, Syringe 1ml (1.7g), XBW
++J022MD0142K7	901472	10003704	G-æniel Universal Injectable, Syringe 1ml (1.7g), BW
++J022MD0142K7	901473	10003705	G-æniel Universal Injectable, Syringe 1ml (1.7g), A1
++J022MD0142K7	901474	10003706	G-æniel Universal Injectable, Syringe 1ml (1.7g), A2
++J022MD0142K7	901475	10003707	G-æniel Universal Injectable, Syringe 1ml (1.7g), A3
++J022MD0142K7	901476	10003708	G-æniel Universal Injectable, Syringe 1ml (1.7g), A3.5
++J022MD0142K7	901477	10003709	G-æniel Universal Injectable, Syringe 1ml (1.7g), A4
++J022MD0142K7	901478	10003710	G-æniel Universal Injectable, Syringe 1ml (1.7g), B1
++J022MD0142K7	901479	10003711	G-æniel Universal Injectable, Syringe 1ml (1.7g), B2
++J022MD0142K7	901480	10003712	G-æniel Universal Injectable, Syringe 1ml (1.7g), CV
++J022MD0142K7	901481	10003713	G-æniel Universal Injectable, Syringe 1ml (1.7g), CVD
++J022MD0142K7	901482	10003714	G-æniel Universal Injectable, Syringe 1ml (1.7g), AO1
++J022MD0142K7	901483	10003715	G-æniel Universal Injectable, Syringe 1ml (1.7g), AO2
++J022MD0142K7	901484	10003716	G-æniel Universal Injectable, Syringe 1ml (1.7g), AO3
++J022MD0142K7	901485	10003717	G-æniel Universal Injectable, Syringe 1ml (1.7g), JE
++J022MD0142K7	901486	10003718	G-æniel Universal Injectable, Syringe 1ml (1.7g), AE
++J022MD0142K7	901487	10003719	G-æniel Universal Injectable, Syringe 1ml (1.7g), XBW EEP



++J022MD0142K7	901488	10003720	G-æniäl Universal Injectable, Syringe 1ml (1.7g), BW EEP
++J022MD0142K7	901489	10003721	G-æniäl Universal Injectable, Syringe 1ml (1.7g), A1 EEP
++J022MD0142K7	901490	10003722	G-æniäl Universal Injectable, Syringe 1ml (1.7g), A2 EEP
++J022MD0142K7	901491	10003723	G-æniäl Universal Injectable, Syringe 1ml (1.7g), A3 EEP
++J022MD0142K7	901492	10003724	G-æniäl Universal Injectable, Syringe 1ml (1.7g), A3.5 EEP
++J022MD0142K7	901493	10003725	G-æniäl Universal Injectable, Syringe 1ml (1.7g), A4 EEP
++J022MD0142K7	901494	10003726	G-æniäl Universal Injectable, Syringe 1ml (1.7g), B1 EEP
++J022MD0142K7	901495	10003727	G-æniäl Universal Injectable, Syringe 1ml (1.7g), B2 EEP
++J022MD0142K7	901496	10003728	G-æniäl Universal Injectable, Syringe 1ml (1.7g), CV EEP
++J022MD0142K7	901497	10003729	C G-æniäl Universal Injectable, Syringe 1ml (1.7g), CVD EEP
++J022MD0142K7	901498	10003730	G-æniäl Universal Injectable, Syringe 1ml (1.7g), AO1 EEP
++J022MD0142K7	901499	10003731	G-æniäl Universal Injectable, Syringe 1ml (1.7g), AO2 EEP
++J022MD0142K7	901500	10003732	G-æniäl Universal Injectable, Syringe 1ml (1.7g), AO3 EEP
++J022MD0142K7	901501	10003733	G-æniäl Universal Injectable, Syringe 1ml (1.7g), JE EEP
++J022MD0142K7	901502	10003734	G-æniäl Universal Injectable, Syringe 1ml (1.7g), AE EEP
++J022MD0142K7	013047	10006896	G-æniäl Universal Injectable, Unitip 15x0.16mL (0.27g), A1
++J022MD0142K7	013048	10006897	G-æniäl Universal Injectable, Unitip 15x0.16mL (0.27g), A2
++J022MD0142K7	013049	10006898	G-æniäl Universal Injectable, Unitip 15x0.16mL (0.27g), A3
++J022MD0142K7	013050	10006899	G-æniäl Universal Injectable, Unitip 15x0.16mL (0.27g), A3.5
++J022MD0142K7	013051	10006900	G-æniäl Universal Injectable, Unitip 15x0.16mL (0.27g), A4
++J022MD0142K7	013052	10006901	G-æniäl Universal Injectable, Unitip 15x0.16mL (0.27g), B1
++J022MD0142K7	013053	10006902	G-æniäl Universal Injectable, Unitip 15x0.16mL (0.27g), B2
++J022MD0142K7	013054	10006903	G-æniäl Universal Injectable, Unitip 15x0.16mL (0.27g), CV
++J022MD0142K7	013055	10006904	G-æniäl Universal Injectable, Unitip 15x0.16mL (0.27g), CVD
++J022MD0142K7	013056	10006905	G-æniäl Universal Injectable, Unitip 15x0.16mL (0.27g), AO1





++J022MD0142K7	013057	10006906	G-ænial Universal Injectable, Unitip 15x0.16mL (0.27g), AO2
++J022MD0142K7	013058	10006907	G-ænial Universal Injectable, Unitip 15x0.16mL (0.27g), AO3
++J022MD0142K7	013059	10006908	G-ænial Universal Injectable, Unitip 15x0.16mL (0.27g), JE
++J022MD0142K7	013060	10006909	G-ænial Universal Injectable, Unitip 15x0.16mL (0.27g), AE
++J022MD0142K7	013061	10006910	G-ænial Universal Injectable, Unitip 15x0.16mL (0.27g), XBW
++J022MD0142K7	013062	10006911	G-ænial Universal Injectable, Unitip 15x0.16mL (0.27g), BW
++J022MD0142K7	901509	10003741	G-ænial Universal Injectable (3x) + G-Premio Bond Kit Promo
++J022MD0142K7	/	10006971	G-ænial Universal Injectable SAMPLE (unitips)
++J022MD0142K7	901616	10004850	G-ænial Universal Injectable A2 PROMO PACK (2XA2)
++J022MD0142K7	901617	10004858	G-ænial Universal Injectable A3 PROMO PACK (2XA3)
++J022MD0142K7	901618	10004949	G-Aenial Univ Injectable A2-A3 PROMO PACK
++J022MD0142K7	/	10006950	G-aenial Univ Injectable + G-Premio Bond 3+1
++J022MD0142K7	/	10006971	G-aenial Universal Injectable MARKETING.SAMPLE
++J022MD0142K7	/	10007248	PROMO G-aenial Universal Injectable + G-aenial A'CHORD, A2, A3 Tips
++J022MD0142K7	901532	10003753	Injection Moulding Kit 1x Exaclear cartridge + 3x G-ænial Universal Injectable (A1, A2 & A3)