



EC DECLARATION OF CONFORMITY
According to Annex V and Annex VII of MDD 93/42/EEC

TF02 09 May 2006
GMDN 16704

GC EUROPE N.V.
Research Park
Interleuvenlaan 33
B-3001 Leuven
Belgium

We ensure and declare under our sole responsibility that the products :

GC Fuji PLUS
GC Fuji PLUS CAPSULE
GC Fuji PLUS EWT

to which this declaration relates are in conformity with the following standards or other normative documents :

EN ISO 13485:2016	Medical devices - Quality management systems -Requirements for regulatory purposes
ISO 9917-2: 2010	Dentistry - Water-based cements – Part 2: Resin-modified cements

and meet the provisions of Council Directive 93/42/EEC concerning Medical Devices which apply to them, and are manufactured in accordance with the technical documentation.

These products are Class IIa according to rule 8 of annex IX of the Council Directive.

Notified Body: British Standards Institution (n°2797).

Leuven, 25/05/2021.....
Date

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Mario Minale
Head of Regulatory Affairs
On behalf of GC EUROPE N.V.



LIST OF PRODUCTS

Article Code	New Article Code	Description
000219	10000084	Fuji Plus powder 15g
000220	10000085	Fuji Plus liquid 7ml
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)
000231	10000088	Fuji Plus EWT powder 15g A3
001409	10000157	GC Fuji PLUS, Intro Package, Full Set, A3 (Content: 15g Powder, 7ml Liquid, 6.5ml conditioner & Accessories)
001410	10000158	Fuji Plus powder Translucent 1
001411	10000159	Fuji Plus powder A3 15g
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)
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)
003210	10000509	Fuji Plus box of 50 caps A3 EE (Content: Box with 50 Capsules, with 0.36g Powder and 0.18g (0.16ml) Liquid each, Mixed Volume per Capsule 0.19ml)
003211	10000510	GC Fuji PLUS, Intro Package, Full Set, A3 EEP (Content: 15g Powder, 7ml Liquid, 6.5ml conditioner & Accessories)
003212	10000511	Fuji Plus powder Yellow 15g EE
003213	10000512	Fuji Plus powder A3 15g EEP
003214	10000513	Fuji Plus powder Translucent 1
003215	10000514	Fuji Plus liquid 7ml EEP
003231	10000521	Fuji Plus EWT powder 15g A3 EE
800126	10001808	GC Fuji Plus Capsule promo
901519	10003751	PROMO Fuji Plus Caps A3 + Freegenol WEP
901520	10003752	PROMO Fuji Plus Caps A3 + Freegenol EEP
900508	10003295	Fuji Plus Capsule A3 promo 50+10 EEP
900507	10003294	GC Fuji Plus Capsule promo 50+10 EEP
800127	10001809	Fuji Plus Capsule A3 promo



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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, 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	Fuji Plus Conditioner
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Ürün Adı	
Verwendungszweck Intended Purpose Usage prévu Uso inteso Izmantošanas mērķis Finalidade prevista Predvideni Namen Hedeflenen Amaç	TOOTH CONDITIONING AGENT
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 6
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	++J022MD0061K6





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

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, 23 Apr 2025

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
++J022MD0061K6	000221	10000086	GC Fuji Plus Conditioner
++J022MD0061K6	003232	10000522	GC Fuji Plus Conditioner EEP